UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

THE TRUSTEES OF THE WELFARE AND PENSION FUNDS OF LOCAL 464A – PENSION FUND, et al., Individually and on Behalf of All Others Similarly Situated, Plaintiffs, vs. MEDTRONIC PLC, HOOMAN HAKAMI, OMAR ISHRAK, BRADLEY LERMAN, GEOFFREY S. MARTHA, KAREN L. PARKHILL, and SEAN SALMON, Defendants.	Civ. No. 0:22-cv-02197-KMM-JFD CLASS ACTION CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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The Phoenix Insurance Company Ltd. and The Phoenix Provident Pension Fund Ltd. ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined in ¶2, *infra*), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' public documents, conference calls, and announcements made by Defendants; U.S. Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Medtronic plc ("Medtronic" or the "Company"); analysts' reports and advisories about the Company; statements by percipient witnesses; and other publicly available information. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all purchasers of Medtronic common stock between May 23, 2019 through May 26, 2022, inclusive (the "Class Period"), which seeks remedies under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule l0b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

II. INTRODUCTION AND SUMMARY OF THE FRAUD

2. This case concerns a straightforward fraudulent scheme – Medtronic and its Chief Executive Officers, Omar Ishrak ("Ishrak") and Geoffrey Martha ("Martha"); Chief

Financial Officer, Karen Parkhill ("Parkhill"); President, Sean Salmon ("Salmon"); General Counsel, Bradley Lerman ("Lerman"); and Executive Vice President, Hooman Hakami ("Hakami") (collectively, "Defendants") engaged in a scheme and made statements and omissions that misrepresented the true state of Medtronic's Diabetes Group.

3. Medtronic is a global healthcare technology company that was, during the Class Period, divided into four business segments, called "Groups." Relevant to this action is the Diabetes Group, which manufactures and sells diabetes products, including the MiniMed insulin pump – Medtronic's flagship product that was responsible for the lion's share of the Diabetes Group's revenues.

4. Leading into and during the Class Period, investors were intently focused on the Diabetes Group. Once hailed as Medtronic's "fastest growing" business segment, the Diabetes Group had grown its global insulin pump market share from 58% in 2009 to about 70% in 2017.[1] Key to this extraordinary growth was the MiniMed 600 Series pumps, and in particular the MiniMed 670G, which was revolutionary when it was released in 2017 and touted by one market observer as one of "Medtronic's most noteworthy clinical accomplishments."

5. Given the Diabetes Group's exponential growth, the market understood that revenues and profits stemming from the group were vital to the Company's success. But leading into the Class Period, Medtronic faced growing competition in the diabetes space and the Diabetes Group's performance was stagnating. Analysts were concerned, and they

[1] Emphasis is added and citations are omitted throughout unless otherwise indicated.

repeatedly questioned Defendants on their plans to "turn this [Group] around." To assuage the market's concern, Defendants assured that they were "***laser-focused*** on doing what it takes to return to market growth" in the Diabetes Group, were "***confident that we can turn it around***," and that doing so was "***a top priority for us***" and a "***key strategic focus***." A central component of this "turnaround" was continuing to sell the MiniMed 600 Series pumps and obtaining Food and Drug Administration ("FDA") approval of the Company's next-generation insulin pump – the MiniMed 780G – which Defendants billed as the product that would resuscitate the Diabetes Group. Unfortunately for, and unknown to, Medtronic's customers and investors, the MiniMed 600 Series pumps were plagued with dangerous quality issues, which caused physicians and patients to flee to competitors' products and further exacerbated the competitive pressures. These concealed product problems threatened the Company's already flagging position in the diabetes market and imperiled FDA approval of the mission critical, next generation MiniMed 780G.

6. Unable to deliver a "turnaround" organically, Defendants resorted to fraud. Defendants' scheme, misrepresentations, and omissions involved two, interrelated frauds – (1) concealed and misrepresented product problems and the resulting negative financial and reputational impact on Medtronic related to the MiniMed 600 Series and older pumps from the beginning of the Class Period through mid-2021, and (2) concealed and misrepresented problems and known uncertainty related to FDA approval of the MiniMed 780G from mid-2021 through the end of the Class Period.

7. Known to Defendants but concealed from customers and investors, all MiniMed 600 Series pump models, including the 670G, featured a defective "retainer ring,"

which was meant to lock together the pump and insulin cartridge. The faulty MiniMed retainer ring prevented the insulin reservoir from properly sealing onto the pump, causing the over- or under-delivery of insulin, and resulting in serious, life-threatening conditions up to and including death. Between June 2016 and November 2019, Medtronic received a flood of more than ***74,000 complaints*** related to the defective retainer ring, yet refused to institute a recall or otherwise alert patients to the dangerous pumps. Defendants justified their say-nothing approach by manipulating the procedures they used to estimate the probability of harm, which kept the estimate artificially low to avoid triggering a recall. During this same period, Defendants were aware of dangerous cybersecurity defects in Medtronic's insulin pumps that left customers vulnerable to hacking and unauthorized injections of insulin, yet refused to inform their customers, initiate a recall, or even conduct an investigation into the vulnerability. As a further part of their scheme, Defendants orchestrated and publicized small, controlled studies that they used to advance the false narrative that Medtronic's insulin pumps were safe and effective. Because Defendants were, according to a confidential witness, hands-on managers who attended monthly product review meetings and monitored all developments in the Diabetes Group, Defendants knew of these severe product quality problems and knew that those problems imperiled FDA approval of the MiniMed 780G.

8. In addition to their scheme to conceal and misrepresent the product defects and risk management failures, Defendants repeatedly stated that the Diabetes Group's performance was "driven by" "strong demand" for or the "ongoing launch" of the MiniMed 600 Series pumps. Defendants made these misrepresentations to help minimize and deflect from the product problems, particularly because these problems occurred at the same time

Medtronic's competitors were releasing superior insulin pumps, leaving Medtronic even more vulnerable to market share loss.

9. But Defendants could not hide these dangerous problems forever. In August 2019, Medtronic stealthily began releasing MiniMed 600 Series pumps with updated, supposedly more robust, black retainer rings, but left pumps with the older, less robust clear retainer rings on the market. Shockingly, they did not warn users of the potential dangers posed by their pumps. Then, given the mounting consumer complaints, in November 2019, Medtronic issued a "Field Safety Notification" directing users of only two models of 600 Series pumps to self-examine their pumps' retainer ring and notify the Company if the ring appeared damaged or missing. However, the Company insisted this action was "voluntary" and "not a recall." Despite Defendants' minimization, it became public on February 12, 2020 that the FDA had determined the safety notice was, in fact, a recall, and the most serious kind – a Class I recall. Further, the recall was not limited to the two 600 Series models identified in Medtronic's November 2019 notification, but affected all four models.

10. To stem the tide, Defendants reassured the market that notwithstanding the problems with the 600 Series pumps, the Diabetes Group's turnaround was imminent, citing to the highly anticipated MiniMed 780G pump – the successor product to the 600 Series that was Medtronic's "***live or die product***." Defendants declared that "we're very excited" about it, that Medtronic was "making good progress in terms of our enrollment in the pivotal trial," and that "***[t]he most important product launch we have is the 780G***."

11. The problem, however, was that the retainer ring defect was only the tip of the iceberg. Hidden from the market were multiple additional defects and risk management

failures that rendered timely approval of the MiniMed 780G all but impossible, and it was only a matter of time before this broader set of problems would come to light. In particular, when the FDA learns of a Class I recall, federal regulations dictate that the FDA may initiate an inspection to determine the root cause(s) of the problem. Thus, following the recall of the MiniMed 600 Series pumps, the FDA conducted a month-long inspection of the Diabetes Group's headquarters in Northridge, California, from June 7, 2021 to July 7, 2021. At the conclusion of the inspection, the FDA reported its findings of myriad deficiencies and presented "Management Discussion topics" to Medtronic at a July 7, 2021 "closing meeting." The same day, the FDA detailed its inspection findings on FDA Form 483 (the "Form 483"), delivered to Defendants on July 7, 2021, which documented numerous risk management and reporting failures that were far broader than the retainer ring defect, including that Medtronic: (i) used an incorrect risk threshold when evaluating the danger posed by the 600 Series pumps; (ii) failed to adequately review and investigate complaints regarding failed retainer rings, both the old and the supposedly fixed versions; and (iii) failed to timely notify the FDA of reportable pump malfunctions and resulting serious injuries.

12. These severe, undisclosed findings rendered FDA approval of the MiniMed 780G on the timeline that Defendants had publicly promised all but impossible. Undeterred, and despite their self-characterized "very collaborative" relationship with the FDA, Defendants continued to misleadingly assure investors that the MiniMed 780G was "under active review with the FDA," with Salmon claiming "***things are on track as far as we can tell***," "***we've had very good interactive conversations with FDA***," and "***I think we're making excellent progress there***." Yet, all the while, and undisclosed to investors,

Defendants were sending letters – ***all of which Salmon signed*** – to the FDA regarding the unresolved deficiencies noted in the Form 483. Indeed, according to a confidential witness, Defendants knew following the inspection there was no chance of obtaining timely FDA approval of the MiniMed 780G, but Defendants decided "this information would ***not*** be disseminated to the public before the next analyst call, which was two weeks away."

13. In a last ditch effort to stave off a warning letter from the FDA, on October 5, 2021, Medtronic issued a full recall of any MiniMed 600 Series insulin pump with the old, clear retainer ring, whether or not the ring was damaged. But it was too little too late. Due to Medtronic's widespread, unresolved deficiencies, the FDA formalized its negative findings from its Northridge inspection in a December 9, 2021 warning letter (the "Warning Letter"). The Warning Letter established that Medtronic utilized an incorrect risk threshold when evaluating the danger posed by the 600 Series pumps; failed to adequately review and investigate complaints; failed to adequately review and investigate new complaints regarding the supposedly fixed replacement retainer rings; failed to timely notify the FDA that Medtronic's pumps had caused "reportable serious injury"; and failed to timely notify the FDA of a report that its device may be malfunctioning in a manner "likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Yet Defendants still declined to admit that timely approval of the MiniMed 780G was unlikely, with Martha stating only that it "continue[s] to be under active review with the FDA, with approval subject to our warning letter."

14. When the effects of the scheme and the true extent of the product and approval problems could no longer be concealed, investors were blindsided with a series of negative

disclosures proximately caused by Defendants' scheme, misrepresentations, and omissions. These disclosures began with the February 2020 announcement of the MiniMed 600 Series recall, continued with the December 2021 Warning Letter, and culminated with the May 2022 admission that the MiniMed 780G would not contribute revenue to the Company in fiscal year 2023 due to the deficiencies identified in the Warning Letter. Through these partial disclosures, the truth was slowly revealed regarding the impact of Defendants' scheme, misrepresentations, and omissions on Medtronic, causing its stock price to decline and investors to suffer billions of dollars in monetary damages. But by then, Defendants had already offloaded approximately ***$42.8 million*** worth of personally held Medtronic shares in suspicious, impeccably timed stock sales.

III. JURISDICTION AND VENUE

15. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and SEC Rule 10b-5(a)-(c) promulgated thereunder (17 C.F.R. §240.10b-5). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act.

16. Venue is proper in this district pursuant to 28 U.S.C. §1391(b) and §27 of the Exchange Act. Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this district. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this district. In addition, the Company's principal executive offices are located in this district.

17. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate

commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

IV. THE PARTIES

18. Plaintiff The Phoenix Insurance Company Ltd. and The Phoenix Provident Pension Fund Ltd. purchased Medtronic common stock during the Class Period as set forth in the previously filed certification (ECF 27-2, 27-3) and incorporated herein, and was damaged thereby.

19. Defendant Medtronic plc is an Irish corporation with its principal place of business in Minneapolis, Minnesota. The Company's stock trades on the New York Stock Exchange under the ticker symbol "MDT."

20. Defendant Omar Ishrak was the Company's Chief Executive Officer ("CEO") from June 2011 through April 26, 2020, and thereafter served as Executive Chairman until December 2020.

21. Defendant Geoffrey S. Martha was the Company's President from November 2019 until April 2020. He joined the Company in 2011. Before becoming its President, Martha was Executive Vice President ("EVP") of Medtronic's Restorative Therapies Group. Martha took over for Ishrak as the Company's CEO on April 27, 2020 and Chairman in December 2020.

22. Defendant Karen L. Parkhill is and was the Company's EVP and Chief Financial Officer ("CFO") throughout the Class Period.

23. Defendant Sean Salmon has been the Company's EVP since October 2019 and President of Medtronic's Cardiovascular Portfolio since January 2021. He served as President of Medtronic's Diabetes Group from October 2019 until May 2022.

24. Defendant Bradley Lerman served as Medtronic's Senior Vice President, Corporate Secretary, and General Counsel during the Class Period until he left the Company effective December 31, 2021. According to the Form 8-K filed on June 30, 2021, Lerman had served on the Company's executive committee for over seven years.

25. Defendant Hooman Hakami served as the EVP of the Diabetes Group from May 13, 2014 through October 21, 2019, when he was replaced by Salmon.

V. BACKGROUND TO THE FRAUD

A. Advanced Insulin Pumps and Continuous Glucose Monitors

26. Before animal cells can burn glucose for energy, the glucose first needs to enter the cell. In humans and many other mammals, insulin is a hormone produced by the pancreas that causes cells to become porous to glucose, thereby regulating the amount absorbed by cells or present in the bloodstream. Diabetes is the disease of this system, and it can occur in two types. Type 1 diabetes develops when pancreatic cells are mistakenly destroyed by the body's immune system, leaving the body with insufficient, or no, insulin. In Type 2 diabetes, the body produces sufficient insulin, but the body's cells have stopped responding to it, leaving them impermeable to glucose. More than 95% of people with diabetes have Type 2, which is far easier to treat, usually requiring only medication and lifestyle changes.

27. For the 5% of diabetes patients globally – and an estimated 1.45 million in the United States alone – with Type 1, management of the disease is more complex, requiring precisely calibrated infusions of insulin. In non-diabetic healthy adults, blood glucose concentrations typically range between 80-120 milligrams per deciliter ("mg/dL"). Straying outside the range in either direction is dangerous. Hyperglycemia (blood glucose concentrations that are too high) can result in neuropathy, retinopathy, blindness, and other complications. Hypoglycemia (blood glucose concentrations that are too low) is dangerous within minutes and can be fatal within hours, as the glucose-starved heart and brain cells begin to die, causing fatal arrhythmias and seizures.

28. For decades, common practice was to inject insulin manually, via syringe, multiple times a day. The advent of the insulin pump, however, simplified diabetes management. Insulin pumps lock onto an accompanying insulin cartridge using a part called a "retainer ring." Rather than introducing several units of insulin into the body all at once via injection, insulin pumps allow a constant drip of miniscule, calibrated amounts of insulin over time, resulting in vastly better control over blood glucose levels, and increasing the amount of time a diabetic can spend with their blood glucose level within the target range (sometimes referred to as "time in range"). The baseline drip of insulin is called the "basal rate." At mealtimes, to control the resulting blood glucose spike, a one-time delivery of insulin is required. Such a delivery is called a "bolus."

29. Insulin pumps must be precise. If the insulin cartridge is not locked firmly into place, *e.g.*, due to a faulty or damaged retainer ring or software error, under- or over-delivery of insulin can occur. Delivering too much insulin can cause hypoglycemia, resulting in a

near-immediate medical emergency. Until recently, insulin pumps had no way of knowing what the patient's blood glucose level was – they simply responded to the wearer's commands, delivering a set basal rate and boluses as directed. The most advanced pumps can integrate with continuous glucose monitors ("CGMs"), which are worn on the body and constantly monitor the wearer's blood glucose level. Combining a CGM with a pump results in what the industry calls a "hybrid closed loop system," which can adjust the basal rate of insulin in response to changes in the user's blood glucose level. They cannot, however, deliver automatic boluses at mealtimes. Pumps that can deliver such boluses are called "advanced hybrid closed loop systems," and might come close to achieving what the human pancreas does effortlessly – respond to changes in blood glucose levels in real time, even after meals, and deliver calibrated amounts of insulin with little to no intervention from the user.

B. Medtronic and Its Diabetes Group

30. Founded in a Minnesotan garage in 1949, Medtronic is now an Irish company with its headquarters and principal place of business in Minneapolis, Minnesota. Medtronic describes itself as "the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions." Doing so is lucrative: for fiscal year 2020 ("FY20"),[2] the Company reported nearly $30

[2] Medtronic's fiscal year (or "FY") ends on the last Friday in April of each calendar year and begins immediately thereafter. Thus, the first quarter (or "Q1") of each fiscal year ends on the last Friday in July of the preceding calendar year, the second quarter (or "Q2") ends on the last Friday in October of the preceding calendar year, the third quarter (or "Q3") ends on the last Friday in January of the current calendar year, and the fourth quarter (or "Q4") and the FY itself end on the last Friday in April of the current calendar year. For example,

billion in net sales, over $2 billion spent on research and development, 90 thousand employees worldwide, over 49 thousand patents, and over 72 million patients served.

31. At the start of the Class Period, Medtronic organized itself into four reportable business units, which it called "Groups": Cardiac and Vascular; Minimally Invasive Therapies; Restorative Therapies; and Diabetes. Three of the four groups contain subdivisions, as follows:

Group	Division
Cardiac and Vascular	Cardiac Rhythm & Heart Failure
	Coronary & Structural Heart
	Aortic, Peripheral & Venous
Minimally Invasive Therapies	Surgical Innovations
	Respiratory, Gastrointestinal & Renal
Restorative Therapies	Brain Therapies
	Pain Therapies
	Spine
	Specialty Therapies
Diabetes	*-no subdivisions-*[3]

32. Historically, the Diabetes Group contributed billions of dollars in top-line revenue to the Company, generating between $2.1 billion and $2.4 billion in each FY18,

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Q1 2020 covered the period from April 27, 2019 to July 26, 2019; Q2 2020 covered July 27, 2019 to October 25, 2019; Q3 2020 covered October 26, 2019 to January 31, 2020; and Q4 2020 covered February 1, 2020 to April 24, 2020.

[3] For less than a year, the Diabetes Group had two subdivisions: Advanced Insulin Management and Emerging Technologies. This reorganization was announced in Medtronic's August 21, 2018 press release; the final mention of these subdivisions occurred in Medtronic's Form 8-K filed on May 23, 2019. All subsequent SEC filings and press releases make no mention of those subdivisions.

FY19, and FY20. The Diabetes Group was also Medtronic's fastest growing segment in 2018, with one analyst highlighting "momentum in this [diabetes] franchise." A July 21, 2017 article entitled "Medtronic's Diabetes Segment Generating Excitement," similarly noted that the Diabetes Group was Medtronic's "fastest growing segment in the company's portfolio" and that "[i]nvestors are excited about its prospects due to the 670G insulin pump." Globally, Medtronic's Diabetes Group was a heavyweight. In 2009, Medtronic had 58% of global insulin pump market share; the next four biggest players were Roche Diagnostics (12%), Johnson & Johnson (11%), Insulet Corporation (10%), and Deltec (6%). By 2017, Medtronic was estimated to have 70% of the insulin pump market.

33. Coming into the Class Period, Medtronic's flagship insulin pumps were the MiniMed 600 Series, including models 620G, 630G, 640G, and 670G. Released in 2017, the 670G was the first pump from any manufacturer to integrate a CGM, thus becoming a "hybrid closed loop system." One publication touted the 670G under the headline "Artificial Pancreas," calling it one of "Medtronic's most noteworthy clinical accomplishments." With its ability to adjust the basal rate in response to changes in blood glucose levels, the 670G was expected to help the Diabetes Group stave off intensifying competition and maintain Medtronic's dominant status in the market. As relevant here, the MiniMed 600 Series models used the same overall pump body design and would eventually all be subject to the same recall.

34. The MiniMed 670G was of particular importance to Medtronic. Leading into and during the Class Period, Defendants repeatedly touted the MiniMed 670G as almost singlehandedly buoying the otherwise floundering Diabetes Group. For instance, on June

21, 2019, Medtronic's Form 10-K reporting FY19 results stated the Diabetes Group's net sales growth of 12% year-over-year ("YoY") to $2.4 billion "was primarily attributable to the continued demand for the MiniMed 670G hybrid closed loop system." This continued quarter after quarter, with the Company stating that the Diabetes Group's financial performance in each quarter of FY20 was "primarily attributable" to or "driven by" "strong demand" for, or the "ongoing launch" of, the MiniMed 670G.

C. As Competitors Pull Ahead, Medtronic Announces the Next-Generation MiniMed 780G Pump and Shuffles Company Leadership

35. Despite the MiniMed 670G's strong showing in FY19 and FY20, the Diabetes Group's performance overall was stagnating. One hindrance: the MiniMed 670G was not an advanced hybrid closed-loop system. In fact, to date there is only one such commercially available pump that has been approved for use in the United States – produced by Tandem, a Medtronic competitor in the diabetes space.

36. Tandem Diabetes Care is a Delaware company whose products compete directly with Medtronic's. Its principal offices are located in San Diego, California. Tandem began as a relatively small competitor, reporting just under $500 million in total sales for its FY20.[4] In contrast, Medtronic's Diabetes Group alone reported nearly five times as much during its own FY20. But the numbers also reveal that Tandem and its ilk threatened to decimate Medtronic's control of the diabetes market: While Medtronic's

[4] Tandem's fiscal year coincides with the calendar year, unlike Medtronic's. The statistics included in this paragraph therefore refer to slightly different, but comparable, time periods.

Diabetes Group had been stagnant or even declining, Tandem's was exploding, reporting $184 million in sales in 2018, $362 million in 2019, and $499 million in 2020.

37. Tandem calls its flagship pump the "t:slim X2." The first iteration of the t:slim X2 was seen as a competitor to Medtronic's then-current MiniMed 670G when it was released in 2016. Medtronic's answer to Tandem's superior product was the MiniMed 780G. Almost immediately upon announcing the Company's "pivotal trial" of the 780G on June 8, 2019, Medtronic began pointing to it as the Company's next-generation insulin pump and touting its advantages over Tandem's product. The 780G was Medtronic's advanced hybrid closed-loop system and, according to the Company, it would be capable of over-the-air updates, iterative algorithm improvements, and Bluetooth connectivity.

38. Analysts were hopeful that Medtronic could level the playing field against Tandem. On June 9, 2019, UBS wrote that Medtronic "thinks the 780G performance could top 670G and beat out competitors like t:slim X2." Per UBS, Medtronic expected the 780G to have "time in range of >80% vs. the mid 70% range for t:slim and to target glucose levels of 100 mg/dL in the night and day vs. times when TNDM [Tandem] levels can reach 120 and 160 mg/dL in those periods, respectively." Another supposed advantage was Medtronic's superior software, which would allow "780G's average time in auto mode [to] be ~99% vs. 91% for TNDM and [to] have automated meal handling, potentially giving MDT ease of use and clinical advantages." Barclays reported similarly:

> Management . . . is excited about the upcoming product launches in its pumps – next up is the MiniMed 780G, which is the advanced hybrid closed loop system. This product is expected to receive FDA approval around the end of FY20 . . . . Medtronic provided a comparison in its slide deck of 780G to Tandem Diabetes's t:slim X2 with Control-IQ (its next generation device

> under FDA review) across a number of parameters and believes the 780G system will be superior. Beyond 780G, the company is working on a personalized closed loop system as well, with an estimated FDA submission date in 2H FY21.

39. As pressure from competitors in the diabetes space continued to mount, Medtronic decided it was time to show Hakami, head of the Diabetes Group, the door, and in October 2019, Medtronic announced that he was leaving the Company. One market observer noted that Hakami's five-year tenure as head of the Diabetes Group "saw continuous glucose monitor devices like Dexcom's G6 and Abbott's FreeStyle Libre grow in popularity as insulin pump offerings like Tandem Diabetes's t:slim X2 and Insulet's Omnipod also posted big gains." The observer also highlighted Medtronic's battle against its competitors:

> Combined CGM and pump sales for Medtronic last quarter totaled $592 million while Dexcom and Abbott reached about $336 million and $496 million, respectively, ***on CGM sales alone*** in their most recently reported earnings. Tandem's quarterly pump sales recently hit $93.3 million, up 173% year over year, and Insulet's reached $177.1 million, up 43%.

40. Market analysts commented on Hakami's abrupt departure, attributing it to the Diabetes Group's underperformance and the need for a turnaround. An analyst at Morgan Stanley commented on October 19, 2019, "Salmon replaces Hooman Hakami . . . . Group leadership changes at Medtronic are rare, but this is a proactive move that most investors should support." The report considered the replacement "necessary" for Medtronic to "execute the [business] plan that's on the table." Similarly, an analyst at Barclays commented on October 21, 2019, "[g]iven Diabetes missteps in the past, not surprising to see a change in leadership."

41. One month later, on November 19, 2019, the Company hosted its first earnings call since announcing that Martha would be taking over from Ishrak as CEO effective April 27, 2020. On the call, Ishrak invited Martha "to say a few words." In his first public address as incoming CEO, Martha acknowledged that "***[r]einvigorating our Diabetes business is also a priority***" and that Medtronic needed to "get back to leading the innovation in this space." Ishrak also fielded questions from analysts about the MiniMed 780G launch timeline, reassuring investors that "we're very excited" about it, that it "promises to be an outstanding product," that Medtronic was "making good progress in terms of our enrollment in the pivotal trial," that the "next-generation hardware" had already been submitted to the FDA for approval, and, in fact, that ***"[t]he most important product launch we have is the 780G***." Martha also confirmed, "[t]here's no signal to us that things will be unnecessarily delayed or anything like that," and "I don't see anything out of the ordinary here."

42. Then, on December 13, 2019, Tandem left Medtronic even further behind, announcing the latest iteration of its flagship product: the t:slim X2 "with Control-IQ technology," which was "the first system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar." The Control-IQ upgrade was the first, and remains the only, commercially available advanced hybrid closed-loop system. Better still – for Tandem and its users – the new software would be made available to "[a]ll in-warranty t:slim X2 pump users in the United States . . . via remote software update."

43. Tandem's December 13, 2019 announcement was, for Medtronic, a rout. John Sheridan, Tandem's president and CEO, claimed his new product was "'the most advanced

automated insulin dosing system commercially available in the world today.'" Analysts agreed. On November 15, 2019, Merrill Lynch wrote that the forthcoming MiniMed 780G was the only product that could "match" – but not beat – Tandem's Control IQ. Morgan Stanley was blunter, stating on November 20, 2019, "Medtronic's US revenues declined ~7% as the company saw a drop-off in new patient starts in pumps due to competitive pressure." The analyst at Morgan Stanley concluded that Medtronic was hemorrhaging market share to Tandem and another competitor, Insulet, who grew pump sales by 84% and 34%, respectively, in the third quarter of 2019 because their devices were simply more advanced: "We expect new pump patients to continue choosing t:slim (expected to launch with Control-IQ in partnership with Dexcom in the near-term) and Omnipod (especially given Insulet's disruptive [pay-as-you-go] model and ongoing shift to pharmacy distribution) over 670G until the 780G is launched in 2020." Based on Defendants' promises, analysts at Morgan Stanley believed that the launch of 780G "remain[ed] on track to launch in late FY20."

44. Two months later, on January 13, 2020, Morgan Stanley "continue[d] to see risk" in Medtronic's loss of market share. That risk only got more acute as the MiniMed 780G still failed to arrive in the United States. Analysts consistently pinned their hopes on the 780G to rescue the Diabetes Group's declining sales and parroted Company management's insistence that it was on track for approval. For example, a November 20, 2019 Oppenheimer analyst stated:

> Pump hardware has been submitted to FDA; estimated 780G approval timing remains by FY20-year-end . . . . US declines (-6.9%) were driven by competitive pressure.

Analysts similarly focused on the launch of the MiniMed 780G into 2020:

> Evercore ISI, January 13, 2020: "Regulatory timelines for 780G . . . [are] reaffirmed."
>
> Deutsche Bank, February 18, 2020: "As expected, Diabetes was once again weak . . . . The US business promises to remain weak near-term owing to continued competitive headwinds as MDT awaits regulatory clearances of key products including the next-gen 780G pump."
>
> Credit Suisse, May 14, 2020: "We see the U.S. declining at a faster rate (-20%) vs. OUS (-11%) given ongoing competitive pressures . . . . We expect to get an update on regulatory filings and the upcoming launch of the 780G diabetes pump."
>
> Wells Fargo, August 25, 2020: "[M]anagement expects to launch [the 780G] this Fall. . . . commercialization of 780G should provide a big step forward."
>
> JP Morgan, November 24, 2020: "The US 780G launch has been frustratingly delayed this year, partly due to COVID, but the adult and pediatric filings should finally be submitted this quarter."

As delays plagued the product, analysts focused on obtaining 780G approval in FY22:

> J.P. Morgan, August 16, 2021: "[T]here are a few important near-term product and data catalysts to keep on your radar. . . . the US approval of the 780G diabetes pump, which has been sitting at the FDA for some time now.*** We expect any commentary on the call to focus on . . . progress made toward approval for 780G[.]"
>
> Guggenheim, August 24, 2021: "We'll listen for updates on this morning's call about the status of the 780G FDA submission . . . ."
>
> Jefferies, August 24, 2021: "[T]he launch of the 780G/Guardian 4 in the EU and FDA approval likely in FY'22 will better position MDT to go on the offensive."

45. Thus, as Medtronic's analysts and investors pined for the release of the MiniMed 780G to deliver the Diabetes Group from its woes, others acknowledged that competitors' products had "take[n] center stage" and that Medtronic needed to "plot[] a path back to pump dominance." But what explained the "frustrating" years-long delay in

approval for MiniMed 780G while Tandem's advanced hybrid closed-loop pump and the Insulet Omnipod continued to wrest market share from Medtronic? Unbeknownst to investors, it was not simply that competitors had purportedly commercially available pumps on the market that gave them a competitive edge. Instead, a major problem had been brewing in the Diabetes Group that was both driving Medtronic's customers to its competitors' products and rendered timely approval of the 780G in the United States all but impossible – truths Defendants schemed to conceal from investors.

VI. DEFENDANTS' SCHEME AND FRAUDULENT COURSE OF BUSINESS

46. In order to convince the market that the Diabetes Group was turning around, Defendants engaged in a scheme involving violations of federal regulations, half-truths, artifices, and concealment with the twin goals of: (1) concealing from the market ongoing problems with Medtronic's current portfolio of insulin pumps and (2) convincing the market that the highly anticipated MiniMed 780G would obtain timely FDA approval. Defendants concealed and understated pervasive and dangerous malfunctions occurring in the MiniMed 600 Series, MiniMed 508, and Paradigm insulin pumps, and knowingly failed to remove dangerous products from the market. They furthered their scheme of keeping investors and customers in the dark by implementing inappropriate risk analysis methodology that plainly underestimated the risk of harm to users. They also orchestrated several controlled, small-scale studies that touted the benefits of a limited number of functioning MiniMed 600 Series insulin pumps to users. When the truth concerning the financial and reputational ramifications concealed by the scheme was exposed through a series of partial disclosures

including a Class I recall of the MiniMed 600 Series, a Warning Letter, and ultimately the inability to obtain timely FDA approval for the MiniMed 780G, investors suffered substantial monetary damages.

A. Medtronic Knows Its Insulin Pumps Have a Dangerous Defect and Uses Improper Risk Analysis Procedures to Hide It

47. While Defendants told investors that the 670G was singlehandedly buoying the Diabetes Group and touted the 780G's forthcoming approval, they had secretly been confronted – for years – by a flood of complaints regarding the MiniMed 600 Series pumps. Known to Defendants but concealed from the public, Medtronic's 600 Series pumps were plagued with a potentially life-threatening manufacturing defect with their clear retainer ring. Malfunctioning retainer rings could cause the insulin reservoir not to seat properly. With an improperly seated reservoir, the pump could unexpectedly deliver more or less insulin than commanded by the user, resulting in life-threatening hyper- or hypoglycemia.

48. Medtronic was aware of this problem no later than June 2016, when it initiated an internal study to address complaints regarding failing retainer rings on the 600 Series pumps. The FDA, when writing about this internal study in December 2021, said that the Company understated the risk posed by this defect and failed to warn customers of the potential for hazardous failure of the pumps. The "outcomes" of Medtronic's "risk assessment do not appear to be appropriate," the FDA wrote, and Medtronic's "risk calculation formula underestimated the probability of occurrence of harm[.]"

49. Medtronic's risk analysis calculations, conducted upon discovering pervasive and dangerous malfunctions with respect to the retainer rings in the MiniMed 600 Series

pumps, inappropriately and consistently underestimated the likelihood that those pumps would harm existing patients. Moreover, Defendants made the decision to not notify customers about the pervasive and dangerous malfunctions for ***three years*** based on their inappropriate risk analysis.

50. Beginning in June 2016, Medtronic received thousands of complaints from customers regarding the MiniMed 600 Series retainer rings. In total, Medtronic received "***over 74,000 retainer ring complaints***, with over 57,000 of those reported to the FDA" as Medical Device Reports ("MDRs"), by November 2019. In November 2019, Medtronic received at least one report that a patient was hospitalized with a defective 600 Series pump, and ***one report of a death*** "which we have investigated and have been unable to exclude as being associated with this issue."

51. Nonetheless, Medtronic did not notify MiniMed 600 Series users of the true scope of the problems with its insulin pumps until it was forced to institute a full recall of the 600 Series in October 2021, as discussed below. *Infra*, §VI.D.-E. The Company justified the decision to stay silent based on the results of a flawed risk analysis protocol implemented to determine the risk associated with the complaints Medtronic was receiving about the malfunctioning retainer rings. The result of the faulty risk analysis protocol was the erroneous determination that "the risk of serious adverse health consequences was 'improbable.'"

52. Defendants used the results of this protocol, beginning in June 2016 and continuing through November 20, 2019, to justify their decision to keep customers and investors in the dark about the very real and serious danger posed by the MiniMed 600 Series

pumps. Indeed, Medtronic initially considered informing customers of the ongoing malfunction of its pumps, but changed course and instead decided it would not do so.

53. According to the FDA's findings in December 2021, Medtronic's "outcomes of risk assessment ***[did] not appear to be appropriate***." The FDA found that Medtronic's initial risk assessment used a "risk calculation formula [which] underestimated the probability of occurrence of harm" and that "[c]onsequently, [Medtronic] did not initiate a correction or removal to address the defective devices."

54. As time went on and the number of complaints mounted, Medtronic repeated its assessment in November 2019, March 2020, and August 2020. To continue justifying its silence, all of these assessments used the same flawed calculation, which resulted in an artificially low probability of harm – even after a significant increase in complaints.

55. Eventually, with complaints mounting, Medtronic had to manipulate the risk assessment protocol it had initiated in June 2016 to avoid elevating the calculated probability of harm. Specifically, Medtronic revised the formula in March 2021 in two important respects, the combination of which allowed the Company to repeat its flawed risk assessment and conclude the risk of serious adverse health consequences was "improbable," despite receiving tens of thousands of customer complaints. First, Medtronic used the "Total Shipment of Affected Product" as its total population of MiniMed 600 Series devices. However, this metric was improper because it included devices that were not in use by patients, such as those that had been shipped to distributors but had not yet been distributed to customers, thereby artificially increasing the number of units in use. Second, Medtronic increased the parameters on the risk evaluation matrix. This had the practical effect of

requiring a higher occurrence for a harm to be classified as more serious (and thereby trigger the duty to initiate a recall).

56. By making these changes, Medtronic was able to manufacture an estimated probability of harm that was low enough to justify its refusal to recall MiniMed 600 Series pumps using the clear, less robust retainer rings. Despite an ever-growing number of customer complaints, the alterations to the risk analysis protocol resulted in yet another internal determination, in June 2021, that harm was unlikely, which Medtronic again used to justify not warning users of the potential danger. The result of this, according to the Warning Letter, was that Medtronic "failed to adequately remove the pumps containing the older, less robust ring from the market."

B. Medtronic Is Aware of Dangerous Cybersecurity Defects in Its Insulin Pumps, Yet Refuses to Fully Inform Customers, Initiate a Full Recall, or Conduct Proper Investigations

57. In 2018, Medtronic initiated an internal study into a "cybersecurity vulnerability with the remote controllers used with [its] Medtronic MiniMed 508 Insulin Infusion Pump and [its] MiniMed Paradigm Insulin Infusion Pumps." This vulnerability allowed "unauthorized individuals" to access the software of the products in question in ways that could, according to Medtronic's internal investigation, "***result in catastrophic harm to patients***." However, upon making this determination, Medtronic elected to leave these vulnerable devices on the market without informing its customers of the "safety issue."

58. The FDA found that Medtronic's determination violated federal regulations, because although Medtronic destroyed its current inventory of the vulnerable remotes and recalled just over 15,000 of the units that had been shipped in the four years prior to 2018,

Medtronic had been selling remotes susceptible to the cybersecurity breach in question for nearly 20 years – since 1999 – meaning that there were numerous dangerous products still in use. Crucially, according to the Warning Letter, Medtronic "did not notify all customers of this safety issue."

59. These failures to take dangerous products out of circulation and notify customers of the relevant safety issue violated 21 CFR §820.100(a).

60. Medtronic also violated 21 CFR §820.198(c) by failing to adequately investigate at least one report of a data breach. On December 25, 2019, a user of a Paradigm insulin pump sent a complaint to Medtronic, recounting an instance in which the customer received over-injections of "insulin that were not programmed by the customer." However, even though the device in question was returned to Medtronic for analysis, Medtronic's "investigation did not include reviewing the actual pump history to verify" the cause of the unauthorized injection. Instead, Medtronic's cybersecurity Incident Response Management Team, which was tasked with investigating this complaint, closed the investigation in June 2021 after concluding that the cause of the event could not be determined. By doing so, Medtronic perpetuated the appearance that its diabetes products were safe and effective by keeping crucial information about potential cybersecurity vulnerabilities from customers and looking the other way when faced with customer complaints.

C. Medtronic Conducts and Publicizes Small, Controlled Studies Touting the Safety and Efficacy of the MiniMed 600 Series Pumps

61. While Defendants were manipulating the results of Medtronic's risk analysis protocol and concealing the MiniMed 600 Series' defects, they simultaneously orchestrated

and publicized small, controlled studies that they used to advance the false narrative that Medtronic's insulin pumps were safe.

62. In July 2018, after receiving tens of thousands of complaints, Medtronic issued a press release regarding a study it conducted over the course of one year with 6,000 patients in cooperation with the insurance company UnitedHealthcare. This press release cited clinical results compiled by Pratik Agrawal, a data scientist employed by Medtronic, and touted the ability of the MiniMed 630G to "demonstrate 27 percent fewer preventable hospital admissions" compared to diabetes patients who manually inject insulin. (As discussed below, just over a year after Medtronic released the results of this study, Medtronic issued a safety notification regarding the MiniMed 630G and the FDA later classified that notice as a Class I recall. *Infra*, §VI.D.)

63. Medtronic continued the charade when, on May 9, 2019, it announced the results of yet another study: the Study of MiniMed 640G Insulin Pump with SmartGuard TM in Prevention of Low Glucose Events in adults with Type 1 Diabetes, or the "SMILE" study. This study followed just 153 adults as they used the MiniMed 640G and purported to find that using the MiniMed pumps helped increase health outcomes for diabetics. The press release announcing the results stated that "***the SMILE study demonstrated the effectiveness of the [MiniMed 640G] system in reducing hypoglycemia***." (As discussed below, the FDA recalled the MiniMed 640G nine months later. *Infra* §VI.D.)

64. These studies obfuscated the actual state of safety and reliability among the larger population of MiniMed 600 Series pumps. As Medtronic kept quiet regarding the growing number of dangerous malfunctions, the orchestration and publication of these

studies presented a misleading picture to customers, the FDA, and investors regarding the safety and efficacy of Medtronic's insulin pumps.

D. Medtronic Issues Incomplete and Misleading Warnings Regarding the MiniMed 600 Series Retainer Rings, Leaving Dangerous Products in Circulation Until the Full Recall in October 2021

65. Eventually, Defendants had to address the defects and dangerous malfunctions in the MiniMed 600 Series products. But they did so as quietly as possible and stopped short of issuing a recall, leaving dangerous products on the market for years.

66. In August 2019, Medtronic began stealthily releasing MiniMed 600 Series pumps with updated, supposedly more robust black retainer rings. However, Medtronic still did not advise users that all previously sold MiniMed pumps contained the older, less robust, clear retainer rings, or that any insulin pumps sold prior to that time could result in harmful and potentially fatal over- or under-injections of insulin as a result of the old retainer rings.

67. Approximately four months after introducing the updated MiniMed 600 Series pumps with the black retainer rings, and more than three years after first becoming aware that the clear rings were dangerously malfunctioning, Medtronic finally informed customers that their insulin pumps were dangerous. On November 21, 2019, the Company issued a Field Safety Notification – a "voluntary" action and not, the Company insisted, a recall – directing users of the 600 Series pumps to examine the pumps' retainer rings and notify the Company if the ring appeared damaged or missing. The Company included photos of reservoirs with a normal ring, a damaged ring, and a missing ring so that users could conduct their own inspection:

Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump

68. Despite the fact that the MiniMed 600 Series pumps utilized the same overall pump body design, the November 2019 Field Safety Notification included only two models: the 630G and 670G.

69. The Field Safety Notification also included a phone number and website to contact the Company for further guidance. However, as the FDA later reported in the Form 483, Medtronic had instructed its employees to tell customers that the "***field action was not a recall***." Medtronic employees were "***also instructed to not replace defective pumps that were outside the warranty period***."

70. Despite the informal warning, on February 7, 2020, the FDA determined that Medtronic's November 2019 Field Safety Notification was, in fact, a Class I recall – the most serious type. According to the FDA, this designation signals there is "a reasonable probability that the use of or exposure to a violative product ***will cause serious adverse health consequences or death***." In addition to the 630G and 670G, the FDA included the 620G and 640G in its recall notices on February 7, 2020, citing the same problems with

"broken or missing retainer ring[s] that prevent[] a proper lock" that could result in incorrect and potentially harmful doses of insulin. The recall was made public on February 12, 2020.[5]

71. Nevertheless, Medtronic downplayed the scope of the problems and misleadingly conveyed that the retainer ring defect was the only problem plaguing its pumps. Analysts took Defendants at their word, highlighting that the recall was limited and would not meaningfully affect the Company going forward. For example, as detailed in a February 12, 2020 Evercore ISI analyst report, issued in response to the recall, Medtronic indicated it "believes the occurrence of 'retainer ring breaking' is less than 0.1%" and it "told its customer[s] that it will replace a small number of pumps that have the damaged rings – cost impact expected to be minimal."

72. Medtronic issued another letter to its customers on March 5, 2020 informing them of an "urgent recall" but downplaying the severity of the designation, writing that "a 'recall' as defined by the FDA 'does not always mean that you stop using the product or return it to the company.'" As long as the retainer ring functioned properly, the Company wrote, it was safe to continue using the pump.

73. Despite these publicized (albeit downplayed) problems, on an earnings call on February 18, 2020, Salmon insisted that the 780G "review is going well" and the Company was "very interactive with the FDA." Ten days later, the Company wrote in its Form 10-Q, filed with the SEC, that notwithstanding the recall and the FDA's concerns regarding the

[5] On February 7, 2020, the FDA issued recall notices for each of the 620G, 630G, 640G, and 670G insulin pumps. The FDA's February 12, 2020 summary included the 630G and 670G, the two models that were distributed in the United States.

safety of that entire line of products, Medtronic expected "sustained strong consumer demand" for the 600 Series.

74. Notably, all of the steps that Medtronic took up to this point in time fell short of fully recalling all MiniMed 600 Series pumps from circulation, even though complaints and reports of injuries to MiniMed 600 Series users continued to flow in about the new, supposedly more robust black retainer rings. Indeed, according to the FDA, "[f]rom December 2019 to May 2021, [Medtronic] received 887 complaints of defective black retainer rings."

75. Moreover, with the issuance of the Class I recall, product liability cases brought by MiniMed consumers proliferated nationwide. For example, on February 21, 2020, a plaintiff filed an action in the United States District Court of South Carolina, alleging that her MiniMed 630G infusion pump had malfunctioned and delivered the entire reservoir of insulin at once, causing her to suffer a hypoglycemic coma and seizures. *Schwartz v. Medtronic Minimed, Inc.*, 8:20-cv-00804 (D.S.C.). On April 20, 2020, several plaintiffs filed a class action in Los Angeles County Superior Court alleging serious injuries following the malfunctions of their MiniMed 600 Series pumps. *Plum v. Medtronic Minimed, Inc., et al.*, 20STCV15293 L.A. Sup. Ct. That case was later coordinated with six other actions, also alleging serious injury following the plaintiffs' use of MiniMed 600 Series pumps. Separately, another plaintiff filed a class action on November 18, 2020 in Los Angeles County Superior Court after his MiniMed pump malfunctioned, causing him to suffer severe hypoglycemia and requiring a paramedic to give him an emergency intravenous infusion of glucose. *Lightner v. Medtronic Minimed, Inc., et al.*, 20STCV44295, Los Angeles Sup. Ct.

In a Kentucky state court case filed July 2, 2020 and later removed to federal court, the plaintiff alleged that her husband's use of the MiniMed 670G insulin pump system caused him "to sustain severe and permanent injuries which resulted in his untimely and wrongful death." *Carter v. Medtronic Inc. et al.*, 4:20-cv-00118-BJB-HBB (W.D. Ky.). In Kansas, a plaintiff brought suit on July 21, 2020 after suffering hypoglycemic encephalopathy when her MiniMed 670G pump malfunctioned, giving her an insulin overdose. *Walsworth v. Medtronic Inc., et al.*, 2:20-cv-02395-SAC-TJJ (D. Kan.). In Illinois, a plaintiff brought an action on October 29, 2020 alleging serious injuries after the retainer ring on his Medtronic MiniMed 630G pump failed to properly lock the reservoir cartridge onto the pump. *Droba v. Medtronic Minimed, Inc., et al.*, 1:20-cv-06421 (N.D. Ill.). Another case involving wrongful death following the use of the MiniMed 670G pump system was filed in Florida on November 3, 2020. *Diaz v. Medtronic Minimed, Inc., et al.*, 1:21-cv-20061-KMM (S.D. Fl.). Another plaintiff in Pennsylvania sued on November 18, 2020 after suffering serious injuries from a hypoglycemic episode while using the MiniMed 670G insulin pump. *Sheldon v. Medtronic, Inc., et al.*, 3:20-cv-02155-RDM (M.D. Pa.).

76. But, unknown to customers and investors, the retainer ring problems identified in the February 2020 recall were just the tip of the iceberg. Eventually, the full magnitude of the issues plaguing the MiniMed pumps would come to light following the FDA's June-July 2021 inspection of the facility where the products were manufactured, and Medtronic's recall would expand in October 2021 to encompass any 600 Series insulin pump with a clear retainer ring – even those that did not have visible damage.

E. The FDA Investigates the Diabetes Group's Northridge Headquarters While Defendants Assure Investors that MiniMed 780G Approval Is "On Track"

77. When the FDA learns of a Class I recall, federal regulations dictate that the FDA may initiate an inspection to determine the root cause(s) of the problem. Accordingly, the FDA conducted an inspection at Medtronic's Northridge facility from June 7 to July 7, 2021.

78. On July 7, 2021, at the conclusion of its inspection, the FDA reported its findings of myriad deficiencies and presented "Management Discussion topics" at a "closing meeting" with Medtronic. The same day, the FDA reported its findings from the inspection in a Form 483, which was delivered to Medtronic's Vice President of Quality, Chirag Tilara. Over eleven pages, the FDA laid out in exacting detail the deficiencies it found in each of three categories of "observations" that went well beyond the already significant manufacturing defects plaguing the MiniMed retainer rings:

> (1) Medtronic failed to establish adequate "procedures for corrective and preventive action" – referring to Medtronic's inappropriate risk analysis procedures;
>
> (2) Medtronic failed to investigate "[c]omplaints involving the possible failure of a device to meet any of its specifications"; and
>
> (3) Medtronic failed to implement "[w]ritten MDR [Medical Device Report] procedures."

The FDA also set out the corrective action that would be necessary to return the facility to compliance. In short, the inspection found that Medtronic had consistently kept customers in the dark and knowingly exposed them to dangerous products while failing to investigate complaints or make required reports to the FDA.

79. Despite systemic problems identified in the Form 483 that impacted ***all*** products manufactured at the Northridge facility and not just the 600 Series pumps, the next month Martha misleadingly told analysts and investors on the Q1 2022 earnings call on August 24, 2021 that the 780G was "under active review with the FDA," and Salmon falsely claimed that "***things are on track as far as we can tell***." Martha and Salmon reiterated these falsehoods during the Q2 2022 earnings call on November 23, 2021. At that time, Martha reiterated that, "[i]n Diabetes, our MiniMed 780G insulin pump . . . continue[s] to be under active review with the FDA." In response to an analyst's question about Defendants' "expectations for the timing of 780G," Salmon bolstered Martha's misrepresentation by stating that "***we've had very good interactive conversations with FDA***" and "***I think we're making excellent progress there***." No mention was made on either date of the FDA's inspection, the FDA's significant findings detailed in the Form 483, or the delay that such findings posed to the approval of the MiniMed 780G pump.

80. There can be no question that Defendants knew about the widespread issues the FDA highlighted in its Form 483. In fact, when they spoke, Medtronic had sent a series of letters to the FDA regarding the Company's failure to return the Northridge facility to compliance. Medtronic sent the FDA letters regarding the deficiencies noted in the Form 483 on, at a minimum, July 28, September 3, October 8, November 5, and December 3, 2021, ***all of which were signed by Salmon***. Then, on October 5, 2021, Medtronic issued a full recall of any MiniMed 600 Series insulin pump with a clear retainer ring, which it would replace "with one that has the updated black retainer ring at no charge."

81. Due to Medtronic's widespread, unresolved deficiencies, on December 9, 2021, the FDA formalized its negative findings from the Northridge inspection in a Warning Letter. The Warning Letter found that Medtronic utilized an incorrect risk threshold when evaluating the danger posed by the 600 Series pumps; failed to adequately review and investigate complaints regarding failed retainer rings; failed to adequately review and investigate new complaints regarding the supposedly fixed replacement retainer rings; failed to timely notify the FDA of a "reportable serious injury" potentially caused by one of Medtronic's defective pumps; and failed to timely notify the FDA of a report that its device may be malfunctioning in a manner "likely to cause or contribute to a death or serious injury, if the malfunction were to recur."

82. In response to the Warning Letter, Martha acknowledged Medtronic was "disappointed" and the Company was "los[ing] share," and stated "timing is difficult to predict" with regard to the MiniMed 780G pump. Yet Martha ***still*** declined to walk back earlier guidance that approval was expected in FY22, saying only that the 780G "continue[s] to be under active review with the FDA, with approval subject to our warning letter." When explicitly asked whether the Warning Letter was "delinked" to the approval process, Martha demurred, again saying that Medtronic has an "ongoing dialogue on the 780G approval." Notably, Martha also confessed that the "issues" identified in the Warning Letter had been "priorities" for Medtronic even before receiving it, and that Medtronic had been "working on these [issues], like as we talked about, for 2 years now, ***even before the warning letter was issued***."

F. Medtronic Repeatedly Fails to Abide by FDA Regulations Requiring It to Report Malfunctioning and Dangerous Products Under 21 C.F.R. §803.50

83. The misconduct described above repeatedly violated federal regulations that required Medtronic to submit reports to the FDA, known as Medical Device Reports or MDRs, documenting the dangers posed by the MiniMed 600 Series pumps. Title 21 of the Code of Federal Regulations states, in relevant part, that manufacturers:

> (a) must report to [the FDA] . . . no later than ***30 calendar days*** after the day that [a manufacturer] receive[s] or otherwise become[s] aware of information, from any source that reasonably suggests that a device [the manufacturer] market[s]:
>
> (1) May have caused or contributed to a death or serious injury or
>
> (2) Has malfunctioned and this device or a similar device that . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F.R. §§803.50(a)(1), (2). The FDA, in its inspection of Medtronic's facility, found violations of both subsections listed above.

84. Medtronic failed to submit any report to the FDA, at any time, upon learning of at least one instance in which a MiniMed 600 Series device may have "caused or contributed to a death or serious injury," in violation of 21 C.F.R. §803.50(a)(1). The Warning Letter provides one "example" of an instance in which the "MiniMed Insulin Pump malfunctioned . . . [such that] treatment received by the patient was necessitated to preclude permanent impairment of a body function or permanent damage to a body structure." Medtronic,

according to the Warning Letter, never submitted a report of this incident, let alone within the required 30 days.[6]

85. The Warning Letter also provided an example of an instance in which Medtronic submitted reports of malfunctioning devices after the required 30 day timeline, in violation of 21 C.F.R. §803.50(a)(2):

> For example, the information included for Complaints #CASE-2018-00270399 and #CASE-2018-00437534 reasonably suggests that your firm's insulin pump malfunctioned (*e.g.*, broken or missing retainer ring) while in use. . . . As such, your firm should have submitted within the required timeframes, an MDR for each MDR reportable event subject of the referenced complaints. ***The corresponding MDRs . . . were received by FDA beyond the required 30 calendar days timeframe***.

86. The misconduct described above was perpetrated as part of Defendants' scheme and course of business designed to mask the true state of affairs in the Diabetes Group. The scheme had the effect of misleading investors about the dire state of the Diabetes Group, the ballooning product quality and safety issues, and the eventual impact on the approval of the MiniMed 780G pump. By concealing the true state of the Diabetes Group, Defendants' scheme maintained artificial inflation in the price of Medtronic stock, and investors suffered damages when the truth concealed by the scheme was revealed through a series of partial disclosures.

[6] The FDA, according to the Warning Letter, learned about Medtronic's failure to submit reports required by 21 C.F.R. §803.50 during its inspection of Medtronic's Northridge facility that took place from June 7, 2021 through July 7, 2021.

VII. DEFENDANTS FAILED TO DISCLOSE "KNOWN TRENDS OR UNCERTAINTIES" IN VIOLATION OF ITEM 303 OF REGULATION S-K

87. Medtronic's SEC filings, including the Form 10-Qs and 10-Ks filed during the Class Period, failed to disclose information required to be disclosed therein under Item 303 of SEC Regulation S-K, 17 C.F.R. §299.303 ("Item 303").[7] Item 303 requires certain disclosures in the "Management's Discussion and Analysis of Financial Condition and Results of Operations," or MD&A, section of a public company's SEC filings. The SEC created specific rules governing the content of MD&A disclosures to provide material historical and prospective disclosures that enable investors and others to assess the financial condition and results of operations of a company, with emphasis on that company's prospects for the future. The SEC has stated:

> [T]he Commission has long recognized the need for a narrative explanation of the financial statements, because a numerical presentation and brief accompanying footnotes alone may be insufficient for an investor to judge the quality of earnings and the likelihood that past performance is indicative of future performance. MD&A is intended to give the investor an opportunity to look at the company through the eyes of management by providing both a short and long-term analysis of the business of the company.
>
> 'It is the responsibility of management to identify and address those key variables and other qualitative and quantitative factors which are peculiar to and necessary for an understanding and evaluation of the individual company.'

88. Among other things, Item 303(a)(3) required Medtronic to disclose the following in the MD&A of its Class Period SEC filings:

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[7] Medtronic's Class Period quarterly SEC filings consisted of Form 10-Ks issued on June 21, 2019, June 19, 2020, and June 25, 2021; and Form 10-Qs issued on August 30, 2019, December 3, 2019, February 28, 2020, September 3, 2020, December 3, 2020, March 5, 2021, September 2, 2021, December 2, 2021, and March 3, 2022.

> (a) [M]aterial events and uncertainties known to management that are reasonably likely to cause reported financial information not to be necessarily indicative of future operating results or of future financial condition;
>
> (b) [A]ny known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations; and
>
> (c) If . . . events that are reasonably likely to cause a material change in the relationship between costs and revenues . . . , the change in the relationship must be disclosed.

17 C.F.R. §229.303.

89. In November 2020, the SEC adopted certain amendments to simplify and enhance the financial disclosure requirements in Regulation S-K, including Item 303. The November 2020 release (No. 33-10890) codifies the MD&A objectives from the SEC's 2003 and 1989 interpretive releases as 303(a), requiring that a registrant must provide a discussion and analysis that allows an investor to see the company "from management's perspective." Such a disclosure must, on the basis of "management's assessment," address matters that are reasonably likely to have a material impact on future operations. The November 2020 release also codifies Item 303(b)(2)(ii), which requires a registrant to disclose: (1) any known trends or uncertainties that have had or are reasonably likely to have a material impact on revenues or income; and (2) any known events that are "reasonably likely to cause a material change in the relationship between costs and revenues." 17 C.F.R. §229.303(b)(2)(ii). Under the "reasonably likely" requirement, the registrant must disclose a known trend or uncertainty if it: (1) is reasonably likely to occur; and (2) would be material to the registrant if it did occur.

90. As detailed below, during the Class Period, Medtronic experienced significant events and uncertainties with respect to its diabetes business. These included: (1) a pervasive malfunction in its Diabetes Group's flagship product – the MiniMed 600 Series pump – which prompted a deluge of complaints, lawsuits, the death of at least one user of a MiniMed 600 Series device, and ultimately resulted in a Class I recall, and (2) an inspection of Medtronic's Northridge facility conducted between June 7 and July 7, 2021, which resulted in the issuance of, first, a Form 483 and, then, a Warning Letter, finding that Medtronic had likely violated federal regulations due to its inadequate response to the malfunctions of the MiniMed 600 Series products and failure to address complaints about several aspects of the functionality of its insulin pumps.[8]

91. These developments constituted "known events, trends and uncertainties" that management reasonably expected to have a material negative financial and reputational impact on Medtronic in the following ways: (1) the sale of knowingly dangerous products was reasonably likely to result in injuries, fatalities, and/or the issuance of a recall, causing financial and reputational harm to Medtronic that would adversely impact revenues; (2) Medtronic continued to discover problems following the Class I recall that further increased

[8] According to the FDA, a "Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts." A warning letter, on the other hand, "notifies a company that the FDA considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and other federal statutes. Warning Letters are only issued for violations of regulatory significance, *i.e.*, those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected."

regulatory scrutiny and jeopardized product approvals and future revenues; and (3) the inspection and issuance of the Form 483 was an event or uncertainty that heightened regulatory scrutiny and uncertainty with respect to the approval of the MiniMed 780G, thereby negatively impacting future revenues.

A. The Pervasive, Consistent, and Dangerous Malfunctions of the MiniMed 600 Series Retainer Rings Constituted a Trend or Uncertainty that Was Likely to Result in Material Financial and Reputational Harm

92. Beginning in June 2016, Medtronic had knowledge of the dangerous nature of the malfunction plaguing the MiniMed 600 Series retainer rings. This knowledge came in the form of an internal study of the problem and more than 74,000 complaints from users of MiniMed 600 Series pumps. The FDA summarized its findings with respect to the danger posed by the malfunctioning retainer rings as follows:

> A damaged retainer ring may result in the over or under-delivery of insulin which may lead to hypoglycemia or hyperglycemia. . . . [The] FDA determined that there was a reasonable probability that the use of, or exposure to, the pumps manufactured with the clear retainer ring would cause ***serious adverse health consequences, including severe hypoglycemia which can result in loss of consciousness, seizure; severe hyperglycemia which can result in diabetic ketoacidosis or hypersmolar hyperglycemic state, metabolic abnormalities; or death***.

93. Indeed, in addition to the many thousands of other complaints it received, Medtronic was made aware of at least one event in which a MiniMed 600 Series device may have caused or contributed to the serious injury or death of its user. On March 27, 2020, Medtronic received a report that a user of a MiniMed 600 Series product "exhibited [a] low

glucose reading of 36 mg/dL[9] . . . [which could have caused] permanent impairment of a body function or permanent damage to a body structure" had the individual not received emergency treatment. Notably, although Medtronic was required under federal law to notify the FDA of this incident within 30 days, it did not do so.

94. While Medtronic was internally aware of the dangerous conditions posed by failing retainer rings in the MiniMed 600 Series pumps, it kept its customers and the investing public in the dark as to the potential dangers posed to MiniMed users. As a result, investors were also unaware of the risks arising from Medtronic's continued sale of a harmful or deadly medical device. Indeed, Medtronic continued to tout the success of the 600 Series years after the Company received thousands of complaints.

95. Ultimately, however, Medtronic's policy of covering up the growing problem with the MiniMed 600 Series retainer rings proved unsustainable, and the inherent risks associated with the widespread sale of a knowingly dangerous product manifested themselves in the form of a product notice that did not disclose the full extent of the problems or provide a full recall of the products. Specifically, on November 21, 2019, Medtronic notified customers that the MiniMed 630G and 670G pumps were being impacted by damaged or faulty retainer rings. On February 7, 2020, the FDA classified the November 21, 2019 announcement as a Class I recall – the most serious kind of recall.

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[9] A healthy blood-glucose level, according to numerous Medtronic Press releases including one published on September 18, 2019 entitled "MiniMed™ 670G System European Real-World Data Shows 73% Time in Range, Beyond Recommended Targets," is around 120 mg/dL, and Medtronic devices are intended to keep the blood-glucose level of users between 70-180 mg/dL.

96. When the FDA publicized the Class I recall on February 12, 2020, numerous news articles discussed how the MiniMed 600 Series products had caused a whole host of previously undisclosed health problems in its users, and resulted in at least one death. For example, an article published by CNN entitled "Medtronic recalls certain MiniMed insulin pumps tied to 1 death" explained that "Medtronic has recalled some of its insulin pumps after injuries and one death were reported due to the device malfunctioning . . . ." Specifically, the article noted that "2,175 injuries and one death" had been reported. Medtronic's stock dropped by more than 2%.

97. In each of the quarterly SEC filings between the start of the Class Period and February 2020 when the FDA announced the Class I recall, Defendants violated the affirmative disclosure duties imposed by Item 303, and thus §10(b) of the Exchange Act, by failing to disclose material information that was known to management regarding the 74,000 complaints and the malfunctioning 600 Series pumps that were likely to cause serious bodily injury or death. The foregoing concealed facts were required to be disclosed in accordance with MD&A disclosure rules because they were "known trends or uncertainties that [Defendants] reasonably expect[ed] [to] have a material . . . unfavorable impact on [Medtronic's] net sales or revenues."

98. Rather than provide the required disclosures, in Medtronic's June 21, 2019 Form 10-K and its August 30, 2019 and December 3, 2019 Form 10-Qs, Defendants made the following MD&A disclosures with respect to the MiniMed 600 Series pumps, which omitted the known trend, event, or uncertainty with respect to the thousands of complaints and the known product defects, in violation of Item 303:

> The Diabetes Group's net sales growth . . . was primarily attributable to the continued demand for the MiniMed 670G hybrid closed loop system . . .
>
> Looking ahead, we expect our Diabetes Group could be affected by the following:
>
> - Continued patient demand for the MiniMed 670G system, the first hybrid closed loop system in the world. The system is powered by SmartGuard technology, which mimics some of the functions of a healthy pancreas by providing two levels of automated insulin delivery, maximizing Time in Range with reduced user input. More than [180,000] trained, active users are benefiting from SmartGuard technology.
>
> - Continued acceptance and future growth internationally for the MiniMed 670G system.

B. Medtronic Continued to Conceal Both New and Existing Problems with Its Insulin Pumps, Which Increased the Likelihood of Further Recalls, FDA Scrutiny, and Regulatory Uncertainty

99. Rather than rectifying problems with the MiniMed 600 Series pumps or recalling all of the defective pumps, the Class I recall served instead to divert attention away from the broader scope of the quality issues afflicting Medtronic's pumps. Problems with the MiniMed 600 Series continued to worsen and multiply, but Medtronic failed to come clean or even, in many cases, properly investigate the quality and safety issues. These issues not only continued to impact user demand for the 600 Series, but also created new uncertainties as to the necessity of further recall action and increased FDA scrutiny in the form of an inspection to uncover the full scope of the problems.

100. Following the recall, Medtronic continued to receive complaints about retainer rings even after the redesign and the implementation of the supposedly more robust "black" retainer rings. According to the Warning Letter, "[f]rom December 2019 to May 2021, [Medtronic] received 887 complaints of defective black retainer rings." Not only did

Medtronic not disclose these complaints to customers or investors, it refused to even investigate them internally. In the Warning Letter, the FDA stated that Medtronic "failed to investigate over 800 complaints of defective black retainer rings." In one example noted by the FDA, on "April 7, 2020, [Medtronic] received a complaint . . . from a customer experiencing a high blood glucose level of 434 mg/dL" in conjunction with a loose retainer ring. Yet, Medtronic determined it would not conduct a formal investigation of this incident. According to the FDA, Medtronic repeatedly declined to conduct formal investigations into the growing complaints regarding the black retainer rings, at least some of which came after users of Medtronic products experienced blood glucose levels far outside what is considered healthy.

101. In addition to complaints about retainer rings, Medtronic knew of a host of additional problems with its insulin pump technology that it did not adequately disclose to the FDA, customers, or investors related to the software used by its products, and failed to properly rectify or investigate these issues. For example, Medtronic received 25 complaints of failure in the "CareLink" software used to track the blood glucose level of users. For 20 of these complaints, the investigation was closed after Medtronic determined that the "software error [was] unknown" even though the FDA could find "no evidence . . . that technical support attempted to determine the version of software used. . . ."

102. Additionally, Medtronic was aware of, but did not disclose, historical problems concerning the data security of its insulin pumps. In particular, Medtronic was aware of a significant number of MiniMed and Paradigm insulin pumps that experienced cyber security malfunctions that were still on the market. Medtronic, in conducting an internal

investigation into this issue in 2018, found that these pumps suffered from a "vulnerability [that allowed] unauthorized individuals" to manipulate the insulin pumps in such a way that would cause "catastrophic harm to patients." Notwithstanding this internal discovery, the FDA's inspection revealed that Medtronic's attempts to rectify this issue fell far short of what was required by federal regulations, as Medtronic only recalled roughly 15,000 pumps during the course of four years of shipments, and "did not notify all customers of this safety issue."

103. Following Medtronic's issuance of the November 2019 Field Safety Notification and the FDA's February 2020 classification of the same as a Class I recall, an inspection of Medtronic's facilities to establish compliance with federal regulations became all but inevitable. Per the FDA Investigations Operations Manual, one of the few bases on which the FDA will conduct a "directed inspection [is] in response to a Class I Recall. . . . The inspection is conducted to determine the root cause and corrective actions addressing the violation(s) associated with the [recalled] product."[10]

104. The FDA Investigations Operations Manual further provides that inspections conducted following the issuance of a Class I recall have the following objectives:

> [T]o identify the root cause for the recall and assure the firm has implemented effective corrective actions to eliminate its recurrence. In some cases, firm management will have conducted its own analysis and reached conclusions

[10] According to industry experts, "FDA will perform ***intense audits*** of Class I recalls and ***will likely conduct inspections and product testing and initiate compliance and enforcement actions***. Even Class II recalls may result in rigorous FDA follow-up activity. Class I and II recalls can also generate ***considerable media attention and congressional interest***." *A Client's Guide to FDA Recalls*, Akin Gump Strauss Hauer & Feld LLP, April 10, 2019, at 5.

> about the problem and its root cause. It is important to verify that the firm's conclusions and judgments, about the root cause of the problem that led to the recall, are discriminating enough to identify the true cause(s) and steps taken are sufficient in depth and scope. Without identifying the true root cause, it will be difficult for the firm to implement an effective corrective action.

Therefore, an inspection conducted following a Class I recall will, in addition to assessing the root causes of the recall, determine whether the firm subject to the recall properly addressed the recall and whether that firm is capable of complying with federal regulations going forward. In this instance, it was reasonably likely that an FDA inspection would uncover the concealed violations of federal regulations as a result of Medtronic's failure to address the problems associated with the recall and to investigate a whole host of other problems with its insulin pumps and risk management procedures.

105. Medtronic was aware that following the recall, the MiniMed 600 Series pumps continued to experience serious malfunctions. Medtronic reasonably expected that an FDA inspection would uncover Medtronic's multiple, additional violations of federal regulations requiring it to submit MDRs within 30 days upon being notified of instances in which one of their insulin pumps likely contributed to severe injury or death of a user.

106. In short, it was reasonably likely that Medtronic's deficient quality assurance and risk assessment procedures would be discovered in an FDA inspection scheduled as a follow-up to the issuance of the Class I recall. Medtronic's continued concealment of both new and historic problems in its diabetes products exposed the Company to significant

regulatory uncertainty, and constituted an event or uncertainty that was required to be disclosed.[11]

107. In fact, the FDA found in its Warning Letter that Medtronic's failure to rectify the problems that led to the Class I recall or "adequately establish procedures for corrective and preventive action [constituted violations of] 21 CFR §820.100(a)."

108. The FDA also found that Defendants did not adequately investigate the vast majority of the 887 complaints that came in after the recall, noting that Medtronic "failed to investigate over 800 complaints of defective black retainer rings." According to the FDA, Medtronic repeatedly declined to conduct formal investigations into the growing complaints regarding the black retainer rings, at least some of which came after users of Medtronic products experienced blood glucose levels far outside what is considered healthy. The FDA

[11] As the SEC has made clear in interpretive guidance concerning Item 303, "financial measures often tell only part of how a company manages its business. Therefore, when preparing MD&A, companies should consider whether disclosure of all key variables and other factors that management uses to manage the business would be material to investors, and therefore required." *Interpretation: Commission Guidance Regarding Management's Discussion and Analysis of Financial Condition and Results of Operation*, Release Nos. 33-8350; 34-48960; FR-72, December 29, 2003. The SEC then provided "regulatory actions or regulatory environment" as examples of non-financial issues that must be disclosed if they could materially impact future performance. *Id.* at n.27. Similarly, as one commentator noted in the context of SEC disclosures made by medical and drug companies that require approval from the FDA, "[a]mong the most important disclosures required by Regulation S-K is Item 303, 'Management's discussion and analysis of financial condition and results of operations[.]'" Joseph G. Milner, *Sunlight and Other Disinfectants*, Food and Drug Law Journal, Vol. 72, No. 1 (2017), at 148. "Given the special risks and uncertainties associated with drug development and FDA approval, drug companies must closely monitor their public statements in order to remain in compliance with the securities disclosure regime," including Item 303 and Rule 10b-5. *Id.* at 153.

concluded that Medtronic's "fail[ures] to review, evaluate, and investigate complaints . . . [constituted violations of] 21 CFR §820.198(c)."

109. In each of the quarterly SEC filings between the issuance of the FDA's Class I recall and the FDA's inspection of the Northridge facility in June 2021, Defendants violated the affirmative disclosure duties imposed by Item 303, and thus §10(b) of the Exchange Act, by failing to disclose material information that was known to management regarding the continuing complaints, broader product problems, and regulatory uncertainty. The foregoing concealed facts were required to be disclosed in accordance with MD&A disclosure rules because they were "known trends or uncertainties that [Defendants] reasonably expect[ed] [to] have a material . . . unfavorable impact on [Medtronic's] net sales or revenues."

110. Rather than make the required disclosures, in Medtronic's June 19, 2020 Form 10-K and February 28, 2020 and September 3, 2020 Form 10-Qs, Defendants made the following MD&A disclosures with respect to the MiniMed 600 Series pumps, but omitted the known trends, events, or uncertainties with respect to the consumer complaints, the full extent of the known product defects, and regulatory uncertainty, in violation of Item 303:

> Looking ahead we expect our Diabetes group could be affected by the following:
>
> - Continued patient demand for the MiniMed 670G system, the first hybrid closed loop system in the world. The system is powered by SmartGuard technology, which mimics some of the functions of a healthy pancreas by providing two levels of automated insulin delivery, maximizing Time in Range with reduced user input . . . .
>
> - Continued . . . future growth internationally for the MiniMed 670G system . . . .

111. Additionally, in Medtronic's December 3, 2020 and March 5, 2021 Form 10-Qs, Defendants made the following MD&A disclosures with respect to the external market pressures facing the Diabetes Group, but failed to disclose the known events or uncertainties with respect to the consumer complaints, the full extent of the product defects, and regulatory uncertainty, in violation of Item 303:

> The Diabetes Group's net sales declines . . . were primarily attributable to the insulin pump business from new patient start delays associated with COVID-19 and continued competitive pressures in the U.S. . . . [and] international markets. . . .
>
> In addition to the general impacts of COVID-19 on our Company as described in the Executive Level Overview, looking ahead we expect our Diabetes Group could be affected by the following:
>
> - Our ability to execute ongoing strategies to develop, gain regulatory approval, commercialize, and gain customer acceptance of new products . . . .

C. The FDA Inspection and Resulting Form 483 Represented an Event or Uncertainty with Respect to the FDA's Approval of the MiniMed 780G

112. The FDA conducted an inspection of the Northridge facility between June 7 and July 7, 2021. As a result of this month-long inspection, the FDA issued a Form 483 on July 7, 2021, which stated that the following "objectionable conditions" were observed by FDA inspectors: (1) "[p]rocedures for corrective and preventive action have not been established" – referring to Medtronic's inappropriate risk analysis procedures; (2) "[c]omplaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary;" and (3) "Written MDR procedures have not been implemented." In short, the inspection found that Medtronic had consistently kept customers in the dark and exposed them to dangerous products at the same time that it failed to

investigate complaints or make required reports to the FDA, and had not implemented proper steps to address these problems.

113. Defendants were aware of the damaging results of the inspection and the Form 483, yet they continued to make statements indicating confidence that the MiniMed 780G was on track for approval. On June 8, 2021, one day after the FDA inspection began, Martha told investors: "we're making steps as we launch our 780G . . . ." On August 24, 2021, nearly two months after Medtronic received the Form 483, and while Medtronic was exchanging correspondence with the FDA about the deficiencies, Martha told investors:

> In Diabetes, the international launch of our MiniMed 780G insulin pump continues to go well. The 780G has the highest reported time in range of any insulin pump. And starting this fall, people with diabetes in many international markets will not only have access to the 780G, but also our no-calibration 7-day Guardian 4 sensor and our 7-day extended infusion set, the longest-lasting set on the market. This complete offering will be highly differentiated and ease patient burden, and we're working to bring this technology to other markets.
>
> ***In the U.S., the 780G and Guardian 4 sensor continue to be under active review with the FDA***.

114. During the same conference call, when responding to a question about the launch of the MiniMed 780G pump, Salmon assured investors that "we'd love to bring that to the U.S. as soon as possible. But things are ***on track*** as far as we can tell."

115. In each of the quarterly SEC filings between the start of the FDA's inspection of the Northridge facility and the receipt of the Warning Letter in December 2021, Defendants violated the affirmative disclosure duties imposed by Item 303, and thus §10(b) of the Exchange Act, by failing to disclose material information that was known to management regarding the fact that: (i) the FDA conducted an inspection of the Diabetes

Group's facilities between June 7 and July 7, 2021; (ii) the month-long inspection resulted in a Form 483 and multiple subsequent correspondence to the FDA regarding the FDA's discovery of potential violations of federal regulations and Medtronic's inability or unwillingness to properly ensure the safety of customers; and (iii) the deficiencies identified in the Form 483 and Warning Letter imperiled the timely approval of the MiniMed 780G system.

116. Rather than make the required disclosures, in Medtronic's June 25, 2021 Form 10-K and September 2, 2021, and December 2, 2021 Form 10-Qs, Defendants made the following MD&A disclosures with respect to the MiniMed 600 Series pumps, but omitted the known events or uncertainties arising from the inspection and Form 483 and their impact on the approval of the MiniMed 780G pump, in violation of Item 303:

> Diabetes net sales [increases/growth] was primarily attributable to [international growth] in integrated CGM . . . .
>
> [L]ooking ahead, we expect Diabetes could be affected by the following:
>
> * * *
>
> - Our ability to successfully develop and obtain regulatory approval of the products within our pipeline, which include our MiniMed 780G insulin pump and the Guardian 4 sensor, which have been submitted to the U.S. FDA.

VIII. DEFENDANTS' MISREPRESENTATIONS AND OMISSIONS

A. Misrepresentations and Omissions Concerning the MiniMed 600 Series Pumps

117. The Class Period begins on May 23, 2019. That day, Medtronic issued its Q4 2019 results on Form 8-K ("Q4 2019 Form 8-K"), signed by Parkhill. In the press release, the Company reported a 13.4% YoY increase in the Diabetes Group's revenue. The Q4

2019 Form 8-K represented that international markets experienced "[s]trong, mid-teens growth . . . driven by the ongoing launch of the MiniMed™ 670G hybrid closed loop insulin pump system with the Guardian™ Sensor 3," which was offset by "increased competition in the U.S."

118. On the earnings call that same day, attended by Martha, Hakami, Parkhill, and Ishrak, Ishrak stated that "in FY '20, we expect to launch the MiniMed 780G, our advanced hybrid closed-loop system with Bluetooth connectivity."

119. Analysts took note of Defendants' positive report. Credit Suisse reported on May 23, 2019 that "Advanced Insulin Management growth was by [sic] driven by integrated CGM and the ongoing MiniMed 670G system launch OUS [outside the United States], offset by difficult comparisons and competitive pressure in the U.S." and that "Insulin Pump growth was solid in F4Q as a result of OUS 670G sales, but the company faced difficult comparisons on pump sales in the U.S."

120. On June 8, 2019, Medtronic announced the initiation of a pivotal trial of the Company's next-generation MiniMed 780G pump. According to Medtronic, the MiniMed 780G represented a significant improvement over the MiniMed 670G because it would "automate the delivery of correction boluses when the user experiences, or is predicted to experience, prolonged high glucose levels based on their sensor readings." Moreover, Medtronic stated that 100% of participants in a feasibility study of the product "rated the MiniMed 780G system as the best therapy they have ever used, and reported their overall satisfaction as extremely satisfied or very satisfied."

121. The next day, June 9, 2019, Ishrak and Hakami participated in the Company's Investor and Analyst Briefing from the American Diabetes Association ("ADA"). During that conference, Hakami stressed that the MiniMed 670G was a significant driver of international revenue growth, one of the three "big components of our overall revenue stream":

> First, the international revenue. When you look at the international revenue. As I mentioned, this is 45% of our global business. We feel very confident and – in this portion of our business' ability to grow and to grow at double-digit rates, and we feel confident about that ability for a number of different reasons. One, if you just look from a financial standpoint historically, we grew double digits in FY '19, number one. ***Number two, we grew double digits in FY '19 largely without the benefit of the 670G in these geographies. So the 670G is just starting to ramp up in Europe, in Australia and other markets around the world***. In addition to the 670G launch dynamics, we also have increased CGM adoption and increased CGM penetration in the international markets, which is a catalyst for growth. So when you take our historical performance, ***the fact that 670G is going to be ramping up even more in FY '20,*** you look at CGM penetration and adoption in these markets, ***we feel very good about our ability to grow 45% of our business in the double-digit category***.

122. On June 21, 2019, Medtronic filed its Annual Report for FY19 on Form 10-K (the "2019 Annual Report"). In it, Defendants reported that the Diabetes Group's net sales for FY19 were $2.4 billion, an increase of 12% over FY18's net sales of $2.1 billion, itself an increase of 11% over FY17. They stated the "net sales growth for fiscal year 2019 was primarily attributable to the continued demand for the MiniMed 670G hybrid closed loop system." And for FY18, they stated the group's 11% YoY growth in net sales "was primarily attributable to increased sales in the U.S. due to continued growth in our customer base through the adoption of the MiniMed 670G hybrid closed loop system. Further, we experienced continued international growth due to strong sales of the MiniMed 640G system

in Europe and Asia Pacific." Defendants underscored the importance of the MiniMed 670G and forthcoming MiniMed 780G by highlighting the products as those whose demand and launch, respectively, could impact the Diabetes Group:

> Looking ahead, we expect our Diabetes Group could be affected by the following:
>
> - ***Continued patient demand for the MiniMed 670G system,*** the first hybrid closed loop system in the world. The system is powered by SmartGuard technology, which mimics some of the functions of a healthy pancreas by providing two levels of automated insulin delivery, maximizing Time in Range with reduced user input. More than 180,000 trained, active users are benefiting from SmartGuard technology.
>
> - ***Continued acceptance and future growth internationally for the MiniMed 670G system***. This system received CE mark in June 2018 and is now commercialized in Canada, Australia, Chile and in certain European countries. The global adoption of sensor-augmented insulin pump systems has resulted in strong sensor attachment rates.
>
> * * *
>
> - Acceptance of the upcoming launch of our advanced hybrid closed loop system, along with the advancement of our Personalized Closed Loop system which was recently granted "Breakthrough Device" designation by the FDA. These technologies feature our next-generation algorithms designed to improve Time in Range by further automating insulin delivery.

123. Ishrak, Parkhill, and Lerman all signed the 2019 Annual Report. In addition, the report contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Ishrak and Parkhill, stating that the financial information contained in the 2019 Annual Report was accurate and disclosed any material changes to the Company's internal control over financial reporting. The certifications also attested that Ishrak and Parkhill had established and maintained disclosure controls and procedures to ensure that material

information about Medtronic was made known to them and that those disclosure controls and procedures were effective.

124. Defendants' positive statements about the MiniMed 670G as a growth driver for the Diabetes Group had analysts taking note. Ahead of Medtronic's announcement of its Q1 2020 results, on August 15, 2019, Credit Suisse offered its expectations of the quarter. As to the Diabetes Group, Credit Suisse reported, "[w]e continue to see growth being driven by the ongoing MiniMed 670G system launch OUS, partially offset by competitive pressure in the U.S. Management expects Diabetes to grow ~5% in F1Q."

125. Defendants continued on this path when, on August 18, 2019, Medtronic filed a Definitive Proxy Statement on Schedule 14A. It stated that "[t]he Diabetes Group grew revenues in the low-double digits (1), driven by patient demand for the MiniMed® 670G hybrid closed loop system, with over 175,000 active users of the system globally."

126. On August 20, 2019, Medtronic reported its Q1 2020 results on Form 8-K, signed by Parkhill. In the press release, the Company highlighted the MiniMed 670G pump's positive contributions to the Company, reporting that the Diabetes Group saw a 5.4% revenue increase, which was "led by international markets, which grew 15.3 percent as reported or 19.8 percent on a constant currency basis, driven by the ongoing launch of the MiniMed™ 670G hybrid closed loop insulin pump system with the Guardian™ Sensor 3."

127. On the earnings call the same day, attended by Martha, Hakami, Parkhill, and Ishrak, Ishrak emphasized the MiniMed 670G's importance as a growth driver during his prepared remarks:

> ***In Diabetes, we grew 5.4%. And this was despite our U.S. business declining mid-single digits because of competitive challenges*** and the difficult comparisons versus the prior year when our U.S. business grew 33%. Our international business, which represents approximately half of our Diabetes revenue, grew 20%. ***The MiniMed 670G, which drove strong growth in the U.S. last year, is now experiencing that strong same strong consumer demand internationally as we launched into new markets. We now have approximately 200,000 people using the 670G system globally***. In addition, we experienced strong adoption of the Guardian Connect Smart CGM system, which grew in the high 80s.

128. Ishrak also informed analysts that Medtronic had "submitted [its] non-adjunctive labeling application to the FDA, and [the Company is] preparing for the launch of the MiniMed 780G, [its] advanced hybrid closed-loop system with Bluetooth connectivity in the second half of this fiscal year."

129. Later in the call, when asked by an analyst why Defendants had lowered guidance for the Diabetes Group despite being "nicely in line this first quarter," Ishrak explained Defendants were being "prudent" because "[w]e've had more competitive pressure than we'd like in the U.S. in the first quarter."

130. Again, analysts took note. On August 30, 2019, Cowen reported that "[w]ithin Diabetes, international markets grew 19.8% on a constant currency basis, propelled by the continued launch of the MiniMed 670G hybrid closed loop system." The same day, BMO Capital Markets listed "[h]ot topics," the first of which was Medtronic's "Diabetes franchise, as y/y comps begin to ease and the pipeline approval for its MiniMed 780G (end-FY20E)."

131. On August 30, 2019, Medtronic reported Q1 2020 results on Form 10-Q, signed by Ishrak and Parkhill, and again touted the strength of the Diabetes Group generally and MiniMed 670G specifically. Defendants reported that net sales for the quarter saw a 3%

YoY increase, and that the growth "***was primarily attributable to growth in international markets resulting from strong consumer demand of the MiniMed 670G***." Defendants continued to underscore the importance of the MiniMed 670G and 780G to the Company by highlighting the products as those whose demand and launch, respectively, could impact the Diabetes Group. They also misleadingly highlighted competition in the U.S. insulin pump market, while omitting the product defects that drove physicians and patients to competitors' products:

> Looking ahead, we expect our Diabetes Group could be affected by the following:
>
> - ***Increasing pump competition in an expanding U.S. market***.
> - ***Continued patient demand for the MiniMed 670G system, the first hybrid closed loop system in the world***. The system is powered by SmartGuard technology, which mimics some of the functions of a healthy pancreas by providing two levels of automated insulin delivery, maximizing Time in Range with reduced user input. Approximately 200,000 trained, active users are benefiting from SmartGuard technology.
> - ***Continued acceptance and future growth internationally for the MiniMed 670G system***. This system received CE mark in June 2018 and is now commercialized in Canada, Australia, Chile and in select European and Central American countries. The global adoption of sensor-augmented insulin pump systems has resulted in strong sensor attachment rates. We expect additional launches in European countries, including Germany and France, during the second quarter of fiscal year 2020.
>
> * * *
>
> - Acceptance of the upcoming launch of our advanced hybrid closed loop system, along with the advancement of our Personalized Closed Loop system which was just granted "Breakthrough Device" designation by the FDA. These technologies feature our next-generation algorithms designed to improve Time in Range by further automating insulin delivery.

132. On September 30, 2019, Medtronic filed a Definitive Proxy Statement on Schedule 14A. It stated that "[t]he Diabetes Group grew revenues in the low-double digits (1), driven by patient demand for the MiniMed® 670G hybrid closed loop system, with over 175,000 active users of the system globally."

133. On November 19, 2019, Medtronic reported its Q2 2020 financial results on Form 8-K, signed by Parkhill. In the press release, Defendants again emphasized MiniMed 670G as a driver of the Diabetes Group's performance, stating the group's "revenue performance was led by international markets, which grew 14.5 percent as reported or 19.3 percent on a constant currency basis, driven by the ongoing launch of the MiniMed™ 670G hybrid closed loop insulin pump system." This growth, Defendants stated, "was offset by high-single digit declines in the U.S., given increased competition as the group awaits its expected upcoming product approvals."

134. During the analyst conference call held on the same day to discuss the Q2 2020 results, Ishrak – with Parkhill and Martha in attendance – reiterated the demand for MiniMed 670G. Ishrak stated the Diabetes Group's "outperformance[]" was due to the MiniMed 670G:

> ***In Diabetes, we grew 4.3%, slightly ahead of our expectations***. Our U.S. business declined in the high single digits, which is anticipated and resulted from competitive challenges while we await our new products. At the same time, ***our international business, which represents just under half of our Diabetes revenue, grew 19%. The MiniMed 670G, which drove strong growth in the U.S. last year, is experiencing that same strong consumer demand as we launch and receive reimbursement in select international markets. This demand is not only driving double-digit growth in insulin pumps, but is also resulting in double-digit growth in recurring revenue from CGM and other consumables.***

135. Parkhill also emphasized the 670G's importance, stating on the call that, "in terms of market share, our installed base is increasing, particularly as we put 670Gs in Europe." Ishrak stated that the Diabetes Group's growth would continue with the anticipated launch of the 670G's next-generation successor, the MiniMed 780G:

> ***I just want to make it very clear that we're very excited about this pipeline. The 780G promises to be an outstanding product***. We're making good progress in terms of our enrollment in the pivotal trial. ***We've already submitted for our next-generation hardware for approval with the FDA. And so that whole pipeline is on track***. And we're going to go through a period of some pressure, especially with new patients in the U.S. But look, there should be no doubt about our enthusiasm for this pipeline and what we see into the future in Diabetes. ***As Geoff [Martha] pointed out earlier, this is an area of focus for us and one that we will win in***.

136. Analysts accepted Defendants' representations, with Cowen reporting on November 19, 2019 that "[w]ithin Diabetes, growth of 4.3% was led by continued strong growth in international markets which increased 19.3% on a constant currency basis as the launch of the MiniMed 670G hybrid closed loop system continues to benefit the segment." Credit Suisse reported similarly, noting "OUS sales account for ~half of total sales and were up 19%, offsetting U.S. competitive pressures. U.S. sales declined HSD due to ongoing competitive pressures" and "Insulin Pump growth was driven by the ongoing OUS MiniMed 670G system launch, offset by competitive pressures in the U.S."

137. Between May 23, 2019 and November 19, 2019, Defendants sold 157,140 of their own Medtronic shares for proceeds of $16,158,867 million:

Defendant	Shares Sold	Avg. Price Per Share	Proceeds
Martha	11,000	$96.05	$1,056,550
Hakami	135,541	$105.63	$14,027,847
Lerman	10,599	$101.17	$1,074,470

138. Defendants' statements and omissions regarding the MiniMed 600 Series and competition in the diabetes space, as set forth in ¶¶117-118, 120-123, 125-129, 131-135, *supra*, were materially misleading and omitted material facts for the following reasons:

(a) between June 2016 and November 20, 2019, Medtronic received over 74,000 customer complaints regarding the retainer rings in the MiniMed 600 Series pumps, with over 57,000 of those reported to the FDA as MDRs;

(b) in June 2016, Medtronic initiated an internal study to address customer complaints regarding failing retainer rings in the MiniMed 600 Series pumps (which it repeated in October 2019), which employed a flawed methodology and thereby understated the risk posed by the defect in order to justify concealing the known defect from customers for three years;

(c) in August 2019, Medtronic stealthily began releasing MiniMed 600 Series pumps with updated, supposedly more robust, black retainer rings, but left pumps with the older, less robust clear retainer rings on the market, and did not warn users of the potential dangers they posed;

(d) on November 21, 2019, ***two days*** after Defendants' November 19, 2019 assurances, Medtronic issued a Field Safety Notification warning customers about serious safety issues associated with the MiniMed 630G and 670G pumps;

(e) the concealed facts detailed in (a)-(d), *supra*, were required to be disclosed in accordance with MD&A disclosure rules, and the failure to disclose the concealed facts violated Item 303;

(f) Defendants' statements detailed in ¶¶121, 131, *supra*, attributing the financial performance of the Diabetes group to the MiniMed 670G, coupled with risk warnings that the "Diabetes Group ***could*** be affected" by "[c]ontinued patient demand for the MiniMed 670G system" or "[c]ontinued acceptance and future growth internationally for the MiniMed 670G system," were materially misleading because at the same time they made these statements, Defendants concealed that product defects were occurring and impacting sales of the MiniMed 600 Series pumps;

(g) Defendants' statements and risk warnings detailed in ¶¶117, 127, 129, 131, 133-134, *supra*, concerning "increased competition" in the U.S. diabetes market omitted that patients were switching to competitor products in part because of the issues plaguing the MiniMed 600 Series pumps; and

(h) CW-1 confirmed that product problems with the MiniMed 670G system resulted in physicians and patients moving to competitor products.

139. Each time each Defendant sold Medtronic shares between May 23, 2019 and November 19, 2019, each Defendant was required to abstain from selling or disclose the adverse information detailed in ¶138(a)-(h), *supra*.

140. Notwithstanding these positive assurances, ***two days later***, on November 21, 2019, Medtronic warned customers about serious potential safety issues associated with the MiniMed 630G and 670G insulin pumps. Medtronic stated it had received reports of loose insulin reservoirs in these MiniMed models caused by broken or missing retainer rings. As Medtronic explained, "[i]f the reservoir is not properly locked into the pump, it could lead to over or under delivery of insulin, which could then result in hypoglycemia or

hyperglycemia." Accordingly, Medtronic instructed MiniMed users to examine their pumps' retainer rings for any damage and to contact the Company if a retainer ring was loose, damaged, or missing.

141. Despite the serious issues with the MiniMed 600 Series, Defendants continued to assure investors that the MiniMed pumps would carry the Diabetes Group and that the forthcoming MiniMed 780G, in particular, would revive Medtronic's competitiveness in the diabetes market. Just two weeks after Medtronic's safety notification, the Company reported Q2 2020 financial results in a December 3, 2019 Form 10-Q, signed by Ishrak and Parkhill, in which the Company touted an increase in the Diabetes Group's net sales for Q1 and Q2 2020, which "was primarily attributable to growth in international markets resulting from strong consumer demand of the MiniMed 670G."

142. On January 13, 2020, during a JPMorgan Healthcare Conference attended by Martha, Parkhill, Ishrak, and Salmon, Ishrak assured investors that the growth attributable to MiniMed products would continue with the launch of MiniMed 780G:

> ***[W]e've got to do some work in diabetes. But in the pump area, in the closed-loop system; this is a product – this is a market that essentially we created 2 or 3 years ago through the launch of the closed-loop system. There's competitors now and we've got some work to do here, but we're really excited about the 780G, which is, again, very close to its launch phase***. The 780G is a product, which has an advanced closed-loop algorithm, one that has better time and range than what we have today, approaching 80% in adult feasibility studies. It will target blood glucose levels of about 100 in average both day and night. Today's sort of state-of-the-art ours is 120. General market is more like 160. So in general performance for the user, it will be better. But in addition to that, it will have a feature set that will allow – that will be more forgiving to user behaviors. We're actually going to be presenting at the ATTD use case studies under extreme conditions and extreme conditions means what happens when the patient misses a meal bolus and how does this product react to that, and we've got some pretty good data

> to share there. So it's going to be more forgiving and that will make a big difference to these patients.
>
> And in addition to that, we'll have the full pivotal trial data at the ADA in June. ***The regulatory time lines are all on track***. The CE mark has been submitted. FDA submission is forthcoming. ***And this is, again, a product that's forthcoming and will move the needle for us in diabetes***.

143. On February 7, 2020, the FDA determined that Medtronic's November 2019 Field Safety Notification was, in fact, a Class I recall. According to the FDA, this designation signals there is "a reasonable probability that the use of or exposure to a violative product ***will cause serious adverse health consequences or death***." In addition to the 630G and 670G, the FDA included the 620G and 640G in its recall notice on February 7, 2020, citing the same problems with "broken or missing retainer ring[s] that prevent[] a proper lock," and thereby administered incorrect and potentially harmful doses of insulin. The recall was made public on February 12, 2020.

144. Six days later, on February 18, 2020, Medtronic issued its Q3 2020 results on Form 8-K, signed by Parkhill. In the press release, Medtronic reported that the Diabetes Group's "revenue performance was led by international markets, which grew 13.7 percent as reported and 15.6 percent constant currency, driven by the ongoing launch of the MiniMed™ 670G hybrid closed loop insulin pump system," which was offset by "low-double digit declines in the U.S." due to "increased competition."

145. On the earnings call the same day, attended by Martha, Parkhill, Ishrak, and Salmon, Ishrak reiterated the same message, touting the "continued adoption of the MiniMed 670G" in the international markets as a growth driver, offset by "anticipated . . . competitive challenges" in Medtronic's U.S. diabetes business, which "declined in the low double digits"

as a result. Ishrak also stated that Medtronic would "file [its] adult clinical data with the FDA in March, which will push expected approval beyond the fiscal year-end."

146. On the call, an analyst asked Salmon for "some thoughts around the time line" with respect to the 780G's approval in the United States, to which Salmon responded,

> ***The 780G is an important catalyst for us to drive growth, and we expect that to begin***. We have filed the CE mark for that device, and we are anticipating, as Omar said, putting the clinical data module in, in the March time frame. That review is going well. ***We're very interactive with FDA. In fact, we'll be meeting with them later this week. And we'll give more update on exactly what the timing is as we get more information on it***.

147. On February 28, 2020, Medtronic reported Q3 2020 results on Form 10-Q, signed by Ishrak and Parkhill. In the Form 10-Q, Medtronic reported net sales for the Diabetes Group "for the three and nine months ended January 24, 2020 were $610 million and $1.8 billion, respectively, which was flat and an increase of 2 percent, respectively, as compared to the corresponding periods in the prior fiscal year." Medtronic attributed the net sales growth for the nine months ended January 24, 2020 "primarily . . . to growth in international markets resulting from sustained strong consumer demand for the MiniMed 670G," offset by declines due to competition in the United States. Defendants continued to underscore the importance of the MiniMed 670G and 780G by highlighting the products as those whose demand and launch, respectively, could impact the Diabetes Group. They also misleadingly highlighted competition in the U.S. insulin pump market:

> Looking ahead, we expect our Diabetes Group could be affected by the following:
>
> - ***Increasing pump competition in an expanding U.S. market***.

- ***Continued patient demand for the MiniMed 670G system, the first hybrid closed loop system in the world***. The system is powered by SmartGuard technology, which mimics some of the functions of a healthy pancreas by providing two levels of automated insulin delivery, maximizing Time in Range with reduced user input. Approximately 200,000 trained, active users are benefiting from SmartGuard technology.

- ***Continued acceptance and future growth internationally for the MiniMed 670G system***. This system received CE mark in June 2018 and is now commercialized in Canada, Australia, Chile and in select European and Central American countries. The global adoption of sensor-augmented insulin pump systems has resulted in strong sensor attachment rates. We expect additional launches in European countries, including Germany and France, during the second quarter of fiscal year 2020.

* * *

- Our ability to execute ongoing strategies to develop, gain regulatory approval, commercialize, and gain customer acceptance of new products, including our MiniMed 780G advanced hybrid closed loop system, as well as our Personalized Closed Loop system that was granted "Breakthrough Device" designation by the U.S. FDA. These technologies feature our next-generation algorithms designed to improve Time in Range by further automating insulin delivery.

148. On May 21, 2020, Medtronic issued its Q4 2020 and FY20 results on Form 8-K, signed by Parkhill. In the press release, Medtronic reported a 9% decrease in Q4 2020 revenue to $570 million and 1% decrease in FY20 revenue to $2.368 billion, which the Company blamed on COVID-related delays. On the earnings call the same day, attended by Martha, Parkhill, Ishrak, and Salmon, Martha sought to assure investors of the Diabetes Group's imminent turnaround. Martha stated, "We're also expecting European approval this quarter of the MiniMed 780G. In the U.S., we anticipate approval this summer of a new

product we're calling MiniMed 770G." Martha further assured investors that the Diabetes Group pipeline was "***adequately derisked***":

> [W]e haven't really managed that [Diabetes Group] business well. I got to kind of accept that critique that we haven't, I don't think. But I – as we put a new leadership in there and we've taken a hard look at it and for me coming in new, it's an opportunity to relook at it. And we did that. ***And I feel really good about the pipeline***. And it's just a matter of time. I mean we're not – in order to kind of catch-up, ***we don't have to invent new things. We just have to execute on our pipeline, and we feel like it's adequately derisked***. And I wish it were sooner, but that's an area we can put a lot more investment in, even than before because I do believe in the market, I do believe in our capabilities there.

149. Parkhill reaffirmed the Diabetes Group's pipeline on June 3, 2020. That day, Parkhill participated at the Jeffries Healthcare Conference, where she stated, "***[W]e're expecting the 780G launch, hopefully, this fiscal year – later in this fiscal year in the U.S.***"

150. On June 19, 2020, Medtronic filed its Annual Report for FY20 on Form 10-K (the "2020 Annual Report"). In it, the Company reported a 1% YoY decline in the Diabetes Group's net sales for FY20, which it "primarily attribute[ed] to the insulin pump business, particularly with competitive pressure in the U.S. and new patient start delays from physician office closings in the fourth quarter of fiscal year 2020 associated with COVID-19." Medtronic also reported that "***[t]hese declines were partially offset by growth in international markets resulting from sustained strong consumer demand for the MiniMed 670G***, as well as the higher sensor attachment and utilization associated with the global adoption of sensor-augmented insulin pump systems." Defendants underscored the MiniMed 600 Series pumps' importance to the Diabetes Group by listing it as four of the

eight items, in addition to the COVID-19 pandemic and competition in the United States, that could impact the Diabetes Group's performance:

> In addition to the general impacts of COVID-19 on our Company as described in the Executive Level Overview, looking ahead we expect our Diabetes Group could be affected by the following:
>
> * * *
>
> - ***Continued pump competition in an expanding U.S. market***.
>
> - ***Continued patient demand for the MiniMed 670G system***, the first hybrid closed loop system in the world. The system is powered by SmartGuard technology, which mimics some of the functions of a healthy pancreas by providing two levels of automated insulin delivery, maximizing Time in Range with reduced user input. As of the end of fiscal year 2020, approximately 249,000 trained, active users are benefiting from SmartGuard technology.
>
> - ***Continued acceptance and future growth internationally for the MiniMed 670G system***. This system received CE mark in June 2018 and is now commercialized in Canada, Australia, Chile and in select European, and Central and South American countries. The global adoption of sensoraugmented insulin pump systems has resulted in strong sensor attachment rates.
>
> - Changes in medical reimbursement policies and programs, along with additional payor coverage of the MiniMed 670G system.
>
> - Our ability to execute ongoing strategies to develop, gain regulatory approval, commercialize, and gain customer acceptance of new products, including our MiniMed 780G advanced hybrid closed loop system, as well as our Personalized Closed Loop system that was granted "Breakthrough Device" designation by the U.S. FDA. These technologies feature our next-generation algorithms designed to improve Time in Range by further automating insulin delivery.

151. Martha, Parkhill, and Lerman all signed the 2020 Annual Report. In addition, the report contained signed SOX certifications by Martha and Parkhill, stating that the

financial information contained in the 2020 Annual Report was accurate and disclosed any material changes to the Company's internal control over financial reporting. The certifications also attested that Martha and Parkhill had established and maintained disclosure controls and procedures to ensure that material information about Medtronic was made known to them and that those disclosure controls and procedures were effective.

152. On August 25, 2020, Defendants reported Q1 2021 results on Form 8-K, signed by Parkhill. The results were disappointing, with Diabetes Group revenues decreasing 5%. Defendants attributed the revenue underperformance to "a delay in new patient starts on insulin pumps and continued competitive pressure."

153. On the earnings call the same day, attended by Martha, Parkhill, and Salmon, Martha reported during his prepared remarks that "[i]n Diabetes, we continue to execute on our near-term pipeline. . . . ***We've received CE Mark approval for our MiniMed 780G advanced hybrid closed-loop system, and we'll launch this fall***."

154. During the question-and-answer portion of the call, an analyst noted that Defendants were "clearly investing heavily in Diabetes" and asked Martha whether the long awaited Diabetes Group's turnaround was "a 3- to 5-year turnaround story? Or is it something we could see in the shorter term?" In response, Martha stated:

> And then speaking on Diabetes, you said 3 to 5 years. I'm not even going to ask Sean this question because I know the answer. It's not 3 to 5 years. It's going to be faster than that. ***And I think when we get 780 out there, it's going to be a big step forward. Like I mentioned, our sensor pipeline, which is the weak spot here, that is – we feel good about that. And again, I wish it were faster, but it isn't 3 to 5 years***.
>
> So – and the rumors about Diabetes, they didn't come from us. I mean, we're committed to this, and we've never blinked, and we're not going to.

155. On September 3, 2020, Medtronic reported Q1 2021 results on Form 10-Q, signed by Martha and Parkhill. In the Form 10-Q, Medtronic reported a net sales decline of $562 million for the quarter, "primarily attributable to the insulin pump business from new patient start delays associated with COVID-19 and continued competitive pressures in the U.S." In the accompanying risk warnings, Medtronic continued to underscore the importance of the 670G and 780G while omitting the known negative trends impacting the former and delaying the latter:

> In addition to the general impacts of COVID-19 on our Company as described in the Executive Level Overview, looking ahead we expect our Diabetes Group could be affected by the following:
>
> * * *
>
> - ***Continued pump competition in an expanding U.S. market***.
>
> - ***Continued patient demand for the MiniMed 670G system***, the first hybrid closed loop system in the world. The system is powered by SmartGuard technology, which mimics some of the functions of a healthy pancreas by providing two levels of automated insulin delivery, with reduced user input. As of July 31, 2020, approximately 240,000 trained, active users are benefiting from SmartGuard technology.
>
> - ***Continued future growth internationally for the MiniMed 670G system***. This system received CE Mark approval in June 2018 and is now commercialized in Canada, Australia, Chile and in select European, and Central and South American countries. The global adoption of sensor-augmented insulin pump systems has resulted in strong sensor attachment rates.
>
> * * *
>
> - ***Our ability to execute ongoing strategies to develop, gain regulatory approval, commercialize, and gain customer acceptance of new products, including our advanced hybrid closed loop system***, as well as our Personalized Closed Loop system that was granted "Breakthrough Device" designation by the U.S. FDA. These

> technologies feature our next-generation algorithms by further automating insulin delivery.

156. During a Wells Fargo Virtual Healthcare Conference on September 10, 2020, attended by Parkhill, an analyst questioned Parkhill on the "cadence" of the 780G's U.S. approval. Parkhill responded, "So I'll say upfront, too, that the same division within the FDA that's responsible for our approvals within Diabetes is also responsible for COVID diagnostics. So obviously, they're very busy. ***But we are working with them to determine the most efficient way for them to review all of our submissions within that business***."

157. On September 14, 2020, Martha participated at the Morgan Stanley Global Healthcare Conference. In response to an analyst's inquiry about why Martha was "so confident that you get back on track in Diabetes faster than most people think, which is going to take several years," Martha stated:

> Yes. I mean, well so look, just to kind of recap this. So Sean [Salmon] went in 6 months or so ago, it seems like a long time, but he – and validated the technologies there.
>
> So one of the things I was concerned about is, is the technology really there? And is our pipeline legit? Him and the team came back, and we spent a lot of time on this, and the answer is yes. Like even in sensors. We have the right chemistry there. We just have to execute on the product development. Sean is excellent at that.
>
> And you're starting to see, ***we're starting to see the internal milestones have accelerated. And we believe that on all fronts, when the 780 comes out, that's going to be a big jump forward for us***. Obviously, the pump – the algorithms already have a lead, and it will take us – and with the Zeus sensor coming out, that will help us on the finger sticks. And then Synergy will add the better form factor and longevity. And so these – we will – and then the holistic, the competitive – the long term, the holistic approach we have here, having all of this, plus our service levels, we feel is going to make us not just competitive, but back to gaining share.

158. On November 24, 2020, Medtronic reported Q2 2020 on Form 8-K, signed by Parkhill. The press release reported "second quarter revenue of $574 million decreased 3.7 percent as reported and 5.0 percent organic. Diabetes Group revenue performance was impacted by a delay in new patient starts on insulin pumps and continued competitive pressure. CGM grew in the mid-single digits." On the earnings call the same day, attended by Martha and Parkhill, Martha assured investors that the Diabetes Group was working its way back to "market growth" as Defendants "***continue[d] to work with the FDA on the most efficient filing strategy for the 780G***."

159. On December 3, 2020, Medtronic filed with the SEC its Form 10-Q reporting on its Q2 2020 performance, signed by Martha and Parkhill. In the Form 10-Q, the Company reported "net sales for the three and six months ended October 30, 2020 were $574 million and $1.1 billion, a decrease of 4 percent as compared to the corresponding periods in the prior fiscal year," which were "primarily attributable to the insulin pump business from new patient start delays associated with COVID-19 and continued competitive pressures in the U.S." Medtronic continued to underscore the importance of the forthcoming 780G:

> In addition to the general impacts of COVID-19 on our Company as described in the Executive Level Overview, looking ahead we expect our Diabetes Group could be affected by the following:
>
> * * *
>
> - ***Continued pump competition in an expanding U.S. market***.
>
> * * *
>
> - ***Continued future growth internationally for the advanced hybrid closed loop system***. The advanced hybrid closed loop system was approved in the European Union (EU) on June 5, 2020, and launched in twelve countries outside the U.S., primarily in Europe, during October

2020. The global adoption of sensor-augmented insulin pump systems has resulted in strong sensor attachment rates.

- ***Our ability to execute ongoing strategies to develop, gain regulatory approval, commercialize, and gain customer acceptance of new products, including our advanced hybrid closed loop system***, as well as our Personalized Closed Loop system that was granted "Breakthrough Device" designation by the U.S. FDA. These technologies feature our next-generation algorithms by further automating insulin delivery.

160. On June 3, 2021, Martha participated at the Sanford C. Bernstein Strategic Decisions Conference. During his prepared remarks, Martha stated:

> We reached important milestones for key products under development, highlighted by – we submitted our Hugo, our soft tissue robot for CE Mark approval, and we filed for our U.S. IDE from the FDA, and we're recently granted IDE approval. ***We also submitted our 780G, our latest insulin pump and our Zeus sensor to the FDA, which is now under active review***.

161. Between November 20, 2019 and August 23, 2021, Martha and Lerman sold 71,140 of their own Medtronic shares for proceeds of $8,281,714 million:

Defendant	Shares Sold	Avg. Price Per Share	Proceeds
Martha	23,212	$122.06	$2,832,572
Lerman	48,034	$117.55	$5,449,142

162. Defendants' statements and omissions regarding the MiniMed 600 Series pumps, competition in the diabetes space, and approval of the MiniMed 780G, as set forth in ¶¶140-142, 144-160, *supra*, were materially misleading and omitted material facts for the following reasons:

(a) between June 2016 and November 20, 2019, Medtronic received over 74,000 customer complaints regarding the retainer rings in the MiniMed 600 Series pumps, with over 57,000 of those reported to the FDA as MDRs;

(b) in June 2016, Medtronic initiated an internal study to address customer complaints regarding failing retainer rings in the MiniMed 600 Series pumps (which it repeated in October 2019, March 2020, and August 2020), which employed a flawed methodology and thereby understated the risk posed by the defect in order to justify concealing the known defect from customers for three years;

(c) in August 2019, Medtronic stealthily began releasing MiniMed 600 Series pumps with updated, supposedly more robust, black retainer rings, but left pumps with the older, less robust clear retainer rings on the market, and did not warn users of the potential dangers they posed;

(d) on November 21, 2019, Medtronic issued a Field Safety Notification warning customers about serious safety issues limited to the MiniMed 630G and 670G pumps, which Medtronic characterized as "voluntary" and not a recall;

(e) from December 2019 to May 2021, Medtronic received 887 complaints concerning the purportedly more robust black retainer rings that were quietly rolled out in August 2019;

(f) on February 7, 2020, the FDA determined that Medtronic's November 2019 Field Safety Notification was, in fact, a serious Class I recall and involved the MiniMed 620G and 640G, in addition to the MiniMed 630G and 670G pumps. The FDA's recall was made public on February 12, 2020;

(g) on March 5, 2020, Medtronic issued another letter to its users informing them of an "urgent recall," but downplayed the severity of the designation, writing that "a

'recall' as defined by the FDA 'does not always mean that you stop using the product or return it to the company'";

(h) in light of escalating customer complaints, Medtronic revised its risk assessment protocol in March 2021 to continue manufacturing an artificially low probability of harm such that Medtronic could avoid a full recall of all MiniMed 600 Series pumps in circulation at the time;

(i) the concealed facts detailed (a)-(h) above were required to be disclosed in accordance with MD&A disclosure rules, and the failure to disclose the concealed facts violated Item 303;

(j) Defendants' statements detailed in ¶¶147, 150, 155, 159, *supra*, attributing the financial performance of Medtronic's Diabetes group to the MiniMed 670G, coupled with risk warnings that Medtronic's "Diabetes Group ***could*** be affected" by "[c]ontinued patient demand for the MiniMed 670G system" or "[c]ontinued acceptance and future growth internationally for the MiniMed 670G system," were materially misleading because at the same time they made these statements, Defendants concealed that product defects were occurring and impacting sales of the MiniMed 600 Series pumps;

(k) Defendants' statements and risk warnings detailed in ¶¶147, 150, 155, 159, *supra*, concerning "increased competition" in the U.S. diabetes market omitted that patients were switching to competitor products in part because of the issues plaguing the MiniMed 600 Series pumps; and

(l) CW-1 confirmed that product problems with the MiniMed 670G system resulted in physicians and patients moving to competitor products; and

(m) Defendants' statements detailed in ¶¶142, 146, 149, 156-158, 160, *supra*, concerning the approval of the MiniMed 780G, including that Medtronic's application was under "active review" on June 3, 2021, omitted that the FDA was days from undertaking a month-long inspection of the Company's Northridge facility that would unearth issues far broader than the MiniMed 600 Series' retainer rings and impact and delay the MiniMed 780G's approval.

163. Each time each Defendant sold Medtronic shares between November 20, 2019 and August 23, 2021, each Defendant had a duty to abstain from selling or disclose the information in ¶¶162(a)-(m), *supra*.

B. Misrepresentations and Omissions Concerning the Status of Approval of the MiniMed 780G Pump

164. As a follow-up to the Class I recall, the FDA conducted an inspection at the Diabetes Group's Northridge headquarters from June 7 to July 7, 2021. As discussed herein, the result of that inspection was a series of deficiencies identified by the FDA and multiple correspondence between Salmon and the FDA concerning the identified deficiencies.

165. On August 24, 2021, after the FDA inspection, receipt of the Form 483, and exchange of multiple letters with the FDA regarding Medtronic's deficiencies, Medtronic issued its Q1 2022 results on Form 8-K. In the press release, Medtronic touted the "strong growth" of the MiniMed 780G system in international markets, reiterated revenue growth guidance, and raised the lower end of its EPS guidance range for fiscal year 2022. On the earnings call that same day, attended by Martha, Parkhill, and Salmon, Martha and Salmon responded to analyst questions regarding the status of Medtronic's application for FDA

approval of the MiniMed 780G. Martha touted the success of 780G in Europe and stated that 780G was "under active review with the FDA," while Salmon described the ongoing discussions with the FDA in a positive light. Both omitted the inspection, the fact that Medtronic had received the Form 483, and Salmon's letters to the FDA discussing serious deficiencies that imperiled the approval of the 780G pump:

> [Anthony Petrone – Jefferies LLC, Research Division]:
>
> * * *
>
> And then just on Diabetes, a few quick follow-ups to Vijay. 780G launch in Europe, is that still on track second half? And then the 780G clearance as well as iCGM designation for stand-alone sensors, is that still expected in the second half?
>
> [Martha]: I'll let Sean answer the diabetes questions.
>
> * * *
>
> On Diabetes, you mentioned 780G in Europe. That is already approved. So I don't know if you meant to say U.S., but ***in Europe, the 780G is on the market and doing really well***. And that's – we're optimistic because we're seeing the performance in Europe. And the best time and range of any pump and the user feedback and the physician feedback has been off the charts positive. So we're excited about that.
>
> But you had a few other questions there about iCGM. And ***maybe I'm assuming maybe your question was 780G in the U.S. though. Maybe, Sean, do you want to take those***?
>
> [Salmon]: Yes. Thanks, Geoff. The combination of the 780G with the [sensor] that doesn't require confirmation, call it non-adjunctive has been filed in the United States and ***we're seeing really good interactive back and forth*** with you. That's really good. But that Europe launch right in the second quarter where you have a no finger stick sensor mix were infusion set and 780G. It's really a nice combination. Of course, we'd love to bring that to the U.S. as soon as possible. ***But things are on track as far as we can tell***. As you may know, that division of FDA has been very busy with COVID, so it's hard to handicap exactly when time lines happen. ***But we do think [we're] making good progress in [the review]***.

166. Analysts took Defendants at their word, issuing reports reiterating that the MiniMed 780G pump was on track for FDA approval in FY22. For example, an August 24, 2021 Barclays report stated, "780G and the G4 sensor are now being actively reviewed by the FDA, which, in our view, means approval could come before the end of this calendar year." An August 24, 2021 Bank of America report stated, "US Approval of 780G . . . . Under 'active review' with FDA as of late May 2021, we anticipate approval in FY21." An August 24, 2021 Jefferies analyst report stated, "[d]espite recent share losses, the launch of the 780G/Guardian 4 in the EU and FDA approval likely in FY'22 will better position MDT to go on the offensive." And an August 25, 2021 Morgan Stanley analyst report stated, "780G is currently under active FDA review, with approval timelines still hard to pinpoint; ***management does view approval prior to year-end 2021 as realistic***."

167. The very next day, on August 25, 2021, Martha sold 11,581 shares at an average price of $132.67 per share for proceeds of $1.5 million.

168. Salmon also sold that same day, selling 7,290 and 21,129 shares at average prices of $134.09 and $134.08 per share, respectively, for proceeds of $3.8 million.

169. On November 23, 2021, while the inspection, Form 483, and Salmon's multiple letters to the FDA remained concealed from the market, Medtronic issued its Q2 2022 results on Form 8-K. In the press release, Medtronic highlighted "[s]trong pump sales," including from sales of the MiniMed 780G system in international markets, but lowered guidance, blaming "the greater-than-expected market impact of the pandemic and healthcare system staffing challenges . . . ." On the earnings call that same day, attended by Martha, Parkhill, and Salmon, Martha referred to the "active review" of the 780G

application, assuring investors that "***our diabetes turnaround is coming***." On the same call, Salmon responded to another analyst question regarding the status of obtaining FDA approval on the 780G pump. Once again, Salmon described positive developments in the ongoing discussions with the FDA and concealed the receipt of the Form 483, the numerous letters detailing the FDA's serious findings concerning the Diabetes Group, and the fact that the deficiencies identified by the FDA imperiled the approval of the 780G system:

> [Lawrence Biegelsen – Wells Fargo Securities, LLC, Research Division]: So one on diabetes. The quarter was in line, but you took down the guidance. Why is that? ***What are your expectations for the timing of 780G*** . . . ?
>
> * * *
>
> [Salmon]: . . . Yes, Larry, so ***nothing different than what we've been talking about all along***. We've got really strong uptake of 780G and Guardians 4 Sensor outside the United States. In the U.S., we have just – we're waiting for that approval to come through, and ***we've had very good interactive conversations with FDA***.
>
> I think we're making excellent progress there.

170. Following the release of Q2 2021 financials and Defendants' comments on the November 23, 2021 earnings call, analysts reiterated Defendants' assurances that the MiniMed 780G pump was on track for FDA approval in FY22. For example, a November 23, 2021 BTIG analyst report stated, "4Q21 – Expected US FDA clearance for 780G in the US." A November 23, 2021 Piper Sandler report stated, "the diabetes franchise is improving a bit and new product[s] are coming (namely 780G in '22)." A November 23, 2021 UBS analyst report described that Medtronic was "***having good conversations with the FDA***" regarding 780G. And a November 27, 2021 Morningstar analyst report stated, "we anticipate FDA approval on the 780g pump" in "spring 2022."

171. On December 15, 2021, the Warning Letter was announced.

172. On January 10, 2022, Martha, Parkhill, and Salmon attended a JPMorgan Healthcare Conference. During the conference, Martha acknowledged that the deficiencies identified in the Warning Letter required "***extensive remediation***" but assured the market that the Company's efforts were "well underway and we're working to resolve the warning letter as quick as possible." On a February 22, 2022 Q3 2022 earnings call attended by Martha, Parkhill, and Salmon, Martha stated that "we're extremely focused on resolving our warning letter and bringing new products to the U.S. market although timing is difficult to predict." On the same call, when asked whether the "warning letter and the delays in Diabetes" would have an impact on FY23 financials, Parkhill declined to directly answer, stating only that "we're working through our planning process as we speak" and that "we are still very committed to our long-range plan." During a March 7, 2022 Cowen Health Care Conference, in response to a question about Medtronic's discussions with the FDA concerning the Warning Letter, Parkhill stated, "[w]e continue to have very good engagement and interaction with the FDA on both the warning letter remediation and on our 780G and Guardian 4 sensor submission . . . we are making excellent progress on that front." These statements omitted that the severity of the problems and delays precluded Medtronic from recognizing revenue on U.S. sales of the MiniMed 780G pump in fiscal year 2023.

173. Between August 24, 2021 and September 30, 2021, Defendants sold 139,922 of their own Medtronic shares for proceeds of $18,380,453 million:

Defendant	Shares Sold	Avg. Price Per Share	Proceeds
Martha	11,581	$132.67	$1,536,451
Salmon	28,419	$134.08	$3,810,492
Lerman	99,922	$130.38	$13,033,509

174. Defendants' statements and omissions regarding the approval of the MiniMed 780G system, as set forth in ¶¶165, 169, 172, *supra*, were materially misleading and omitted material facts for the following reasons:

(a) The Diabetes Group's Northridge facility had been subjected to a month-long FDA inspection from June 7 to July 7, 2021, during which FDA investigators identified myriad, previously undisclosed manufacturing deficiencies and risk management procedure failures;

(b) Defendants were in receipt of the Form 483 indicating manufacturing and risk management deficiencies at the facility responsible for manufacturing the MiniMed 780G system;

(c) Defendants sent multiple correspondence, signed by Salmon, to the FDA addressing the deficiencies identified in the Form 483, but were unsuccessful in convincing the FDA that Medtronic had remediated the multiple deficiencies;

(d) The receipt of the Form 483 and responses thereto created a known risk or uncertainty that the MiniMed 780G system would not receive timely FDA approval;

(e) CW-2 explained that Defendants knew the problems associated with MiniMed 600 Series pumps, including the Form 483 and Warning Letter, would cause a delay in the FDA's approval of the MiniMed 780G pump. CW-2 explained that the recall of the MiniMed 600 series would have a negative impact and cause major delays for all

associated and/or similar products that were in the premarket approval phase, including both the "next generation" pump and the beleaguered MiniMed 600 Series pumps, and that "it was physically impossible to get approval for any product while under a warning letter";

(f) CW-2 explained that they attended monthly meetings between the FDA and Medtronic personnel in which the MiniMed 780G approval timeline was discussed, and that they also attended, along with Parkhill and Salmon, monthly internal meetings where the status of the MiniMed 780 application was discussed. CW-2 further explained that executive management closely monitored the progress of FDA approval for the MiniMed 780G product, remarking that "this was our live or die product";

(g) CW-2 stated that executive management was very hands-on and that "all developments in the Diabetes units were reported up the chain of command to the CEO";

(h) When CW-2 informed executive management that the MiniMed 780G had no chance of obtaining timely approval, they were told that "this information would not be disseminated to the public before the next analyst call, which was two weeks away." CW-2 stated that "executive management did not clearly share MiniMed 780G's progress information with the public." CW-2 stated that executive management knew before receiving the Warning Letter that the MiniMed 780G would not receive timely approval, and that "executive management continued to communicate misinformation to the public" anyway; and

(i) CW-2 explained that in November 2021, problems with FDA approval of the MiniMed 780G system became clear when a different FDA submission was stalled – CW-2 stated that "the FDA gave us a hint that a warning letter was coming."

175. Each time each Defendant sold Medtronic shares between August 24, 2021 and September 30, 2021, each Defendant had a duty to abstain from selling or disclose the information in ¶174(a)-(i), *supra*.

C. Misrepresentations and Omissions Concerning Risk Warnings

176. On June 21, 2019, Medtronic issued its Form 10-K for the fiscal year ended April 26, 2019, signed by Ishrak, Parkhill, and Lerman. The 2019 Annual Report provided the following risk disclosures:

(a) "***We operate in a highly competitive industry and we may be unable to compete effectively***. . . . We believe our ability to compete depends upon many factors both within and beyond our control, including: product performance and reliability; product technology and innovation, product quality and safety, . . . [and] changes to the regulatory environment. Competition may increase as additional companies enter our markets or modify their existing products to compete directly with ours. In addition, academic institutions, governmental agencies and other public and private research organizations also may conduct research, seek patent protection and establish collaborative arrangements for discovery, research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring necessary product technologies. ***From time to time we have lost, and may in the future lose, market share in connection with product problems, physician advisories, safety alerts and publications about our products, which highlights the importance of product quality, product efficacy and quality systems to our business***. In the current environment of managed care, consolidation among health care

providers, increased competition, and declining reimbursement rates, we have been increasingly required to compete on the basis of price. Further, our continued growth and success depend on our ability to develop, acquire and market new and differentiated products, technologies and intellectual property, and as a result we also face competition for marketing, distribution, and collaborative development agreements, establishing relationships with academic and research institutions and licenses to intellectual property. In order to continue to compete effectively, we must continue to create, invest in or acquire advanced technology, incorporate this technology into our proprietary products, obtain regulatory approvals in a timely manner, and manufacture and successfully market our products. Given these factors, we cannot guarantee that we will be able to compete effectively or continue our level of success."

(b) "Both before and after a product is commercially released, ***we have ongoing responsibilities under the U.S. FDA*** and other applicable non-U.S. government agency regulations. For instance, ***many of our facilities and procedures and those of our suppliers are also subject to periodic inspections by the U.S. FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on the U.S. FDA's Form-483, warning letters, or other forms of enforcement. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical products are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such medical products, detain or seize adulterated or misbranded medical products, order a recall, repair, replacement, or refund of such products, refuse to grant pending pre-market approval applications or require certificates***

of non-U.S. governments for exports, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health."

(c) "***Quality problems and product liability claims could lead to recalls or safety alerts, reputational harm, adverse verdicts or costly settlements, and could have a material adverse effect on our business, results of operations, financial condition and cash flows. Quality is extremely important to us and our customers due to the serious and costly consequences of product failure***, and our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical devices. In addition, many of our products are often used in intensive care settings with seriously ill patients and some of the medical devices we manufacture and sell are designed to be implanted in the human body for long periods of time or indefinitely. ***Component failures, manufacturing nonconformances, design defects, off-label use, or inadequate disclosure of product-related risks or product-related information with respect to our products, if they were to occur, could result in an unsafe condition or injury to, or death of, a patient. These problems could lead to recall of, or issuance of a safety alert relating to, our products***, and could result in product liability claims and lawsuits, including class actions, which could ultimately result, in certain cases, in the removal from the body of such products and claims regarding costs associated therewith. Due to the strong name recognition of the Medtronic and Covidien brands, a material adverse event involving one of our products could result in reduced market acceptance and demand for all products within that brand, and could harm our reputation and ability to market products in the future."

(d) "***Strong product quality is critical to the success of our goods and services. If we fall short of these standards and our products are the subject of recalls or safety alerts, our reputation could be damaged, we could lose customers and our revenue and results of operations could decline***. Our success also can depend on our ability to manufacture to exact specification precision-engineered components, subassemblies and finished devices from multiple materials. If our components fail to meet these standards or fail to adapt to evolving standards, our reputation, competitive advantage and market share could be harmed. In certain situations, we may undertake a voluntary recall of products or temporarily shut down production lines based on performance relative to our own internal safety and quality monitoring and testing data."

(e) "Our medical devices and technologies, as well as our business activities, are subject to a complex set of regulations and rigorous enforcement, including by the U.S. FDA, U.S. Department of Justice, Health and Human Services-Office of the Inspector General, and numerous other federal, state, and non-U.S. governmental authorities. ***To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our products***. As a part of the regulatory process of obtaining marketing clearance for new products and new indications for existing products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable clinical data from existing or future clinical trials may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate, and our business, results of operations, financial condition,

and cash flows. ***We cannot guarantee that we will be able to obtain or maintain marketing clearance for our new products or enhancements or modifications to existing products, and the failure to maintain approvals or obtain approval or clearance could have a material adverse effect on our business, results of operations, financial condition and cash flows***."

(f) "[M]any of our products and services include integrated software and information technology that collects data regarding patients or connects to other internal systems." Like all organizations, we routinely experience attempted interference with the integrity of, and interruptions in, our technology systems via events such as cyber-attacks, malicious intrusions, or other breakdowns. The consequences could mean data breaches, interference with the integrity of our products and data, or other significant disruptions. Furthermore, we rely on third-party vendors to supply and/or support certain aspects of our information technology systems and resulting products. As we have seen with recent "Supply Chain Attacks," "[t]these third-party systems could also become vulnerable to cyber-attack, malicious intrusions, breakdowns, interference or other significant disruptions, and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems."

177. On August 30, 2019, Medtronic issued its Q1 2020 financial results on Form 10-Q, signed by Ishrak and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's 2019 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

178. On December 3, 2019, Medtronic issued its Q2 2020 financial results on Form 10-Q, signed by Ishrak and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's 2019 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

179. On February 28, 2020, Medtronic issued its Q3 2020 financial results on Form 10-Q, signed by Ishrak and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's 2019 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

180. On June 19, 2020, Medtronic issues its 10-K for the fiscal year ended April 24, 2020, signed by Martha, Parkhill, and Lerman. The 2020 Annual Report provided the risk factors previously published in Medtronic's 2019 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

181. Defendants' statements and omissions regarding certain risk warnings, as set forth in ¶¶176-180, *supra*, were materially misleading and omitted material facts for the following reasons:

(a) Between June 2016 and November 20, 2019, Medtronic had received more than 74,000 customer complaints concerning the MiniMed 600 Series pumps' retainer rings; in August 2019, Medtronic stealthily began releasing MiniMed 600 Series pumps with updated, supposedly more robust, black retainer rings while leaving pumps with the older, less robust clear retainer rings on the market and not warning users of the potential dangers they posed; and on November 21, 2019, Medtronic sent a safety notification to patients concerning this issue as to two models, which the FDA classified on February 7, 2020 as a

Class I recall affecting all four models of the 600 Series pumps. In addition, as CW-1 explained, the MiniMed 670G suffered from at least four product problems: a retainer ring issue, a blood glucose loop issue, a reservoir clogging issue, and an alarm sounding issue;

(b) Due to the product problems and resulting customer complaints affecting the MiniMed 600 Series pumps, physicians and patients were moving to competitor products;

(c) Medtronic violated the mandatory MDR regulations by failing to report certain MiniMed-related adverse events and product problems to the FDA, including deaths and serious injuries;

(d) Defendants warned of potential risks of losing market share in connection with product problems but concealed that the risk had already materialized;

(e) Defendants warned of potential risks associated with manufacturing nonconformance, design defects, and inadequate disclosure of product-related risks but concealed that such risks had already materialized;

(f) Defendants warned of potential risks associated with data integrity problems but concealed that such risks had already materialized; and

(g) as a result of (a)-(f) above, Defendants' risk warnings were materially false and misleading.

182. On September 2, 2020, Medtronic issued its Q1 2020 financial results on Form 10-Q, signed by Martha and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's 2020 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

183. On December 2, 2020, Medtronic issued its Q2 2020 financial results on Form 10-Q, signed by Martha and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's 2020 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

184. On March 5, 2021, Medtronic issued its Q3 2020 financial results on Form 10-Q, signed by Martha and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's 2020 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

185. On June 25, 2021, Medtronic issued its 10-K for the fiscal year ended April 30, 2021, signed by Martha, Parkhill, and Lerman. The Form 10-K provided the risk factors previously published in Medtronic's 2019 Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

186. On September 2, 2021, Medtronic issued its Q1 2022 financial results on Form 10-Q, signed by Martha and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

187. On December 2, 2021, Medtronic issued its Q2 2022 financial results on Form 10-Q, signed by Martha and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's Annual Report on Form 10-K, including those statements identified in ¶176, *supra*.

188. Defendants' statements and omissions regarding certain risk warnings, as set forth in ¶¶182-187, *supra*, were materially misleading and omitted material facts for the following reasons:

(a) Defendants were aware of the FDA's month-long investigation and were in receipt of the July 7, 2021 Form 483 indicating manufacturing and risk management deficiencies at the facility responsible for manufacturing the MiniMed 780G system at the same time they warned that inspections "can" lead to Form 483s and/or warning letters;

(b) Defendants sent multiple, unsuccessful correspondence to the FDA seeking to remedy the deficiencies identified in the Form 483 at the same time they warned that a determination by the FDA that Medtronic was not in compliance with applicable regulations or that its products posed an unreasonable health risk could jeopardize approval of products or affect sales;

(c) Defendants warned of potential risks associated with manufacturing nonconformance, design defects, and inadequate disclosure of product-related risks but concealed that such risks had already materialized;

(d) Defendants warned of potential risks associated with data integrity problems but concealed that such risks had already materialized; and

(e) as a result of (a)-(d) above, Defendants' risk warnings were materially false and misleading.

D. Omissions in Violation of MD&A Disclosure Rules

189. As detailed above at §VII., Medtronic's SEC filings, including its Form 10-Qs and Form 10-Ks filed during the Class Period, omitted information required to be disclosed

therein under Item 303 of SEC Regulation S-K, 17 C.F.R. §299.303. In particular, Medtronic was required to disclose known material events and uncertainties reasonably likely to affect its future revenues in in the MD&A section of its SEC filings. Defendants' omissions, in violation of Item 303 as described above in §VII., rendered the following Class Period SEC filings materially false and misleading:

(a) June 21, 2019 Form 10-K for the year ended April 26, 2019;

(b) August 30, 2019 Form 10-Q for the quarter ended July 26, 2019;

(c) December 3, 2019 Form 10-Q for the quarter ended October 25, 2019;

(d) February 28, 2020 Form 10-Q for the quarter ended January 24, 2020;

(e) June 19, 2020 Form 10-K for the year ended April 24, 2020;

(f) September 3, 2020 Form 10-Q for the quarter ended July 31, 2020;

(g) December 3, 2020 Form 10-Q for the quarter ended October 30, 2020;

(h) March 5, 2021 Form 10-Q for the quarter ended January 29, 2021;

(i) June 25, 2021 Form 10-K for the year ended April 30, 2021;

(j) September 2, 2021 Form 10-Q for the quarter ended July 30, 2021;

(k) December 2, 2021 Form 10-Q for the quarter ended October 29, 2021; and

(l) March 3, 2022 Form 10-Q for the quarter ended January 28, 2022.

IX. CONFIDENTIAL WITNESS ACCOUNTS

190. Former Medtronic employees have provided information demonstrating that Defendants' Class Period statements were false and misleading and that Defendants knew or recklessly disregarded the falsity or misleading nature of their statements. The CWs include individuals formerly employed at Medtronic during the Class Period, whose accounts

corroborate one another, other sources set forth herein, and facts now admitted by Medtronic. The CWs provided information to Plaintiff's counsel and/or their investigator on a confidential basis and are particularly described by job description, responsibility, and duration of employment, thereby providing sufficient detail to establish their reliability and personal knowledge. As set forth below, the information provided by the CWs supports an inference that Defendants' Class Period statements were false and misleading and that Defendants acted with scienter.

191. Confidential Witness No. 1 ("CW-1") worked as a Diabetes Management Consultant and then Senior Territory Manager from June 2006 through April 2018 and a Principal Territory Manager between April 2018 and January 2022. CW-1 was responsible for the sale of the MiniMed 630G, 670G, and 770G pumps, including addressing product problems and coordinating with physicians and patients regarding issues that arose with the pumps. CW-1 was responsible for selling Medtronic's diabetes products and growing market share. CW-1 explained that during the Class Period, Medtronic faced intense competitive pressure from DexCom Inc., Tandem Diabetes Care, and Insulet Corporation due to those companies' advanced and synergistic insulin delivery technologies. In particular, the integration of DexCom's continuous glucose monitor with Tandem's and Insulet's insulin pumps made them very strong competitors in the market. CW-1 explained that during the Class Period, there were at least four product problems with the MiniMed 670G system – a retainer ring issue, a blood glucose loop issue, a reservoir clogging issue, and an alarm sounding issue. Complaints relating to these issues were reported to a 24-hour helpline. CW-1 explained that these issues resulted in physicians and patients moving to

competitor products. CW-1 stated that the MiniMed problems began when Hakami started to institute huge cost cuts to make the bottom line appear more profitable. CW-1 stated that Hakami "took an axe to the diabetes' operational budget." CW-1 stated, "we weren't selling more units, he [Hakami] was cutting the budget." CW-1 concluded that the MiniMed setbacks began under Hakami's leadership. CW-1 stated that they understood that executive management tracked revenues on a daily basis. This was done using the MM Sales database and, later in 2021, a Salesforce database. CW-1 stated that they departed Medtronic, in part, because they grew tired of having to constantly apologize to physicians and patients for issues with the MiniMed products.

192. Confidential Witness No. 2 ("CW-2") worked as a Senior Director, U.S. Regulatory Affairs, between October 2020 and August 2022. CW-2 managed a team of regulatory employees whose primary responsibilities included obtaining FDA approval for Medtronic devices, including the MiniMed 780G system. CW-2 was primarily responsible for all regulatory submissions related to the MiniMed 780G application after starting employment at Medtronic, and worked exclusively in the Diabetes Group. CW-2 stated that executive management knew before receiving the Warning Letter that the MiniMed 780G would not receive timely approval but stated that "executive management continued to communicate misinformation to the public."[12] CW-2 stated that it would take approximately one to two years to remediate the deficiencies identified in the FDA's Form 483. CW-2

[12] CW-2 included Martha, Parkhill, Salmon, Que Dellara (replaced Salmon as head of Diabetes in May 2022), Austin Domenici (CFO of Diabetes), Chiraq Tilara (Vice President of Quality Management), Ali Dianaty (Vice President of Product Innovation), and Stacey Ellul (Vice President of Global Regulatory Affairs) in "executive management."

remarked, "it was physically impossible to get approval for any product while under a warning letter." CW-2 explained that the recall of the MiniMed 600 Series would have a negative impact and cause major delays for all associated and/or similar products that were in the premarket approval phase. CW-2 went on to explain that they had monthly meetings on the first Friday of each month with the FDA to discuss the progress of the MiniMed 780G application. CW-2 met with the FDA's product managers and branch chiefs to discuss the progress and timelines for the MiniMed 780G system. CW-2 explained that CW-2 coordinated with Dianaty, Ellul, Tilara, and Ito Wu (FDA Branch Chief) on these monthly meetings. CW-2 also explained that CW-2 attended monthly internal meetings, commonly referred to as "product review meetings," where the status of the MiniMed 780G application was discussed. These product review meetings were attended by approximately 150 individuals, including Salmon and Parkhill. CW-2 explained that executive management closely monitored the progress of FDA approval for the MiniMed 780G product, remarking that "this was our live or die product." CW-2 stated that "executive management did not clearly share MiniMed 780G's progress information with the public." CW-2 explained that executive management knew that they were disseminating unrealistic timelines and dates to shareholders. CW-2 stated that they communicated on a weekly basis during and after team meetings with their boss – Ellul, who reported to Salmon, Dianaty, and Dellara throughout the Class Period – who also attended every FDA meeting. CW-2 stated that executive management was very hands-on and that "all developments in the Diabetes units were reported up the chain of command to the CEO." CW-2 stated that they informed executive management that MiniMed 780G had no chance of obtaining timely approval, but CW-2 was

informed that "this information would not be disseminated to the public before the next analyst call, which was two weeks away." CW-2 explained that in November 2021, problems with FDA approval of the MiniMed 780G system became clear when a different FDA submission was stalled – CW-2 stated that "the FDA gave us a hint that a warning letter was coming." CW-2 departed Medtronic, in part, because they did not have faith in executive management and felt executive management propagated misinformation to the public and was unethical.

X. DEFENDANTS ACTED WITH SCIENTER

A. Defendants Admitted that the Product Quality System for the Diabetes Group Was a Longstanding Problem

193. As Medtronic reported in its December 15, 2021 press release, the FDA's "warning letter focuse[d] on the inadequacy of specific medical device quality system requirements at the Northridge facility in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events." Yet, these issues were not suddenly made apparent to Defendants with the Warning Letter. Rather, as Martha admitted while participating on a January 10, 2022 conference call hosted by JP Morgan: "Improving the performance of our Diabetes business, ***including the quality system, is something that we've been working on for the past couple years***." During a February 22, 2022 earnings call, Martha reiterated that the Company had been working on the concealed problems in Diabetes for two years:

> In terms of – look, the dialogue with the FDA is ongoing. I mean, we've got an ongoing dialogue on the 780G approval. We've got an ongoing dialogue on the warning letter. Our priority is – they're both priorities, but our first priority is to work the warning letter issues, and ***we've been working on these, like as we talked about, for 2 years now, even before the warning letter was***

> ***issued***. So the dialogue with – like I said, with the FDA is ongoing, and it's very constructive, I would say.

194. Thus, by their own admission, Defendants had internally recognized that the Diabetes Group's product quality systems, meant to ensure the safety of the MiniMed pumps, had been underperforming for years.

B. The Month-Long Inspection, Form 483, and Post-Inspection Communications with the FDA Reveal Defendants' Knowledge of the Severity in the FDA's Findings, but Defendants Contemporaneously Assured the Market that the Approval of Minimed 780G Was "On Track"

195. From June 7 to July 7, 2021, the FDA conducted an inspection of Medtronic's Northridge facility. According to the FDA's Investigations Operations Manual (the "Manual"), which is "the primary operational guide for FDA employees who perform field investigational activities," the Form 483 "is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts . . . which were observed during the inspection." The Manual provided "general principles" to which Form 483s "should adhere":

> 1. Observations which are listed ***should be significant*** and correlate to regulated products or processes being inspected.
>
> 2. ***Observations of questionable significance should not be listed on the FDA-483 . . . but will be discussed with the firm's management*** so that they understand how uncorrected problems could become a violation.

196. The Manual reiterated that for Form 483s "to be [a] useful and credible document[]," each observation included in the form "should be significant" and "[t]he observations should be ranked in order of significance." The Manual also indicated the steps

investigators should take to make management aware of the issues uncovered during the inspections:

> Investigators and analysts should make every reasonable effort to discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when the FDA 483. . . is issued. This discussion should include those observations, which may be written on the FDA 483. . . and those that will only be discussed with management during the closeout meeting.

197. In accordance with the Manual, the FDA issued the July 7, 2021 Form 483 to Tilara, Medtronic's Vice President of Quality, after it completed its inspection of the Northridge facility. In the Form 483, the FDA cited three "Observations" of product quality shortcomings, that, per the Manual, the FDA investigator had deemed "significant." In the 11-page Form 483, the FDA found: (1) "Procedures for corrective and preventive action have not been adequately established"; (2) "Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary"; and (3) "Written MDR procedures have not been implemented." Particular facts the FDA cited in the Form 483 include:

- Medtronic's Field Product Impact Assessments, meant to calculate the risk associated with the failed retainer rings in the MiniMed 600 Series infusion pumps, repeatedly "used the same ***underestimated calculation for probability of occurrence*** and concluded again that the risk remained in Zone [REDACTED] ***even after a significant increase in complaints***."

- In Medtronic's June 2021 Field Product Impact Assessment, the "probability of occurrence" was "underreported" because Medtronic considered the "Total Shipment of Affected Product" rather than "the number of products actually in the field," and thus included in its calculation "devices that are not in use by patients, thereby under-estimating the probability of occurrence."

- Before Medtronic issued its safety notification regarding the clear retainer ring in November 2019, Medtronic had "received more than [REDACTED] complaints for this retainer ring issue; [REDACTED] complaints were reported to the FDA as Medical Device Reports (MDRs), ***including three deaths*** . . . , [REDACTED] ***serious injuries*** . . . and [REDACTED] malfunctions that could result in death or serious injury if the malfunction was to recur. . . ."

- While Medtronic "sent notifications to all customers with the affected pumps," "Technical Support personnel were instructed to tell customers that this field action was ***not a recall***."

- Medtronic "continue[d] to receive reports of failures with the re-designed black retainer rings." "As of 05/25/2021, your firm [Medtronic] has received [REDACTED] complaints for defective black retainer rings, including [REDACTED] ***complaints reported as serious injury MDRs*** . . . , and [REDACTED] complaints reported as malfunction MDRs . . . . Analysis of the [REDACTED] returned defective devices with the black retainer rings show that ***your firm confirmed the failures, but no formal investigation was initiated***."

- Medtronic "***failed to submit Medical Device Reports*** (MDRs) for [REDACTED] customer complaints (dated 09/23/2016 – 05/12/2021) related to MiniMed 600 Series Insulin pump retainer ring failures where ***the returned product analysis confirmed that the reservoir was unable to lock into place***. . . . all of these complaints were received after the Field Product Impact Assessment (Version A, dated 06/23/2016) concluded that the failure of the ring could potentially result in under delivery of insulin leading to hyperglycemia, severe hyperglycemia, or diabetic ketoacidosis; or over delivery of insulin leading to mild or severe hypoglycemia or death."

- Medtronic "failed to submit [REDACTED] MDRs within [REDACTED] of becoming aware of information that reasonably suggests that MiniMed Infusion pumps may have caused or contributed to a death or serious injury. These MDRs (submitted between February 2020 and June 2021), include [REDACTED] MDRs ***submitted more than 100 days from the aware date***. . . ."

198. On July 7, 2021, the same day that the FDA transmitted this damning evidence to Medtronic, Medtronic and the FDA held a "closeout" or a "closing meeting" led by the FDA investigator.

199. In a letter to the FDA dated July 28, 2021, Salmon and Tilara enclosed an appendix wherein Medtronic "responded to two Management Discussion topics discussed during the closing meeting" and described how it was "taking broad, systemic actions" to address the FDA's findings. Salmon and Tilara copied on the letter Noel Colon, Medtronic's SVP and Chief Quality Officer, and Laura Mauri, MD, Medtronic's SVP and Chief Clinical and Regulatory Officer.

200. Despite this ongoing dialogue and Salmon's acknowledgement to the FDA that Medtronic was "taking broad, systemic actions" to rectify the Diabetes Group's product safety failings, less than a month later, Salmon reported to investors on August 24, 2021 during the Q1 2022 earnings call that "things are on track" for obtaining FDA approval for the MiniMed 780G.

201. Ten days later, on September 3, 2021, Salmon and Tilara, copying Colon and Mauri, sent a letter update to the FDA regarding Medtronic's response to the Form 483. They noted that they had "released the first version of FCA [Field Corrective Action] plans to document the updated recall strategies to (i) retrieve and replace MiniMed 600 Series Infusion Pumps with a clear retainer ring. . . ." They further noted that on August 25, 2021, (the day after Salmon gave his upbeat message to investors regarding the MiniMed 780G's timeline for approval), Medtronic "provided the FDA Recall Coordinator with details of the updated recall strategies." Also on September 3, they "submitted amendments to the 21 CFR 806 Reports associated with the Retainer Ring."

202. On October 5, 2021, Medtronic announced that it was updating its prior recall of the MiniMed 600 series insulin pump with the clear retainer rings and stated that it "will proactively replace all clear retainer ring pumps, whether the ring is damaged or not."

203. On October 8, 2021, Salmon and Tilara, copying Colon and Mauri, sent another letter update to the FDA that summarized further steps Medtronic had purportedly taken in an attempt to address the Form 483. This included an "onsite review . . . held on September 14-16, 2021" by a third party to provide "an objective, independent assessment" of the corrective actions taken by Medtronic. During the third party's three-day review, it "reviewed other related documents and records, interviewed company officials, and observed the returned goods area and failure analysis laboratory." Salmon and Tilara reported to the FDA that the third party issued a report on October 1, 2021 that provided feedback "in two general areas (1) Complaint Handling and Medical Device Reporting; and (2) Design Controls." They noted that Medtronic was "continuing to review [the report] and assess the best path forward to address [the third party's] feedback."

204. On November 5, 2021, Salmon and Tilara, copying Colon and Mauri, sent another letter update to the FDA describing further actions taken in an attempt to address the Form 483. Salmon and Tilara wrote that Medtronic had created new processes and a more rigorous training program for addressing customer complaints. They further advised the FDA that the third party was scheduled for "second onsite review" to assess Medtronic's corrective actions.

205. While Defendants continued their letter campaign attempting to mollify the FDA on the issues identified in the Form 483, Defendants kept investors in the dark. On

November 23, 2021, during the Q2 2022 earnings call, Martha assured investors that "our MiniMed 780G insulin pump, combined with our Guardian 4 sensor, continue to be under active review with the FDA." Despite the huge uncertainty that existed in gaining FDA approval of the MiniMed 780G due to the MiniMed product quality problems, Salmon nevertheless affirmed to investors:

> We've got [a] really strong uptake of 780F and Guardians 4 Sensor outside the United States. In the U.S., we have just – we're waiting for that approval to come through, and ***we've had very good interactive conversations with FDA***.
>
> I think we're making excellent progress there.

206. On December 3, 2021, Salmon and Tilara, again copying Colon and Mauri, sent another letter update to the FDA summarizing further actions Medtronic had taken in an attempt to remediate the Form 483 findings.

207. But the FDA saw through Medtronic's attempts to paper over the years of product quality failings. On December 9, 2021, the FDA issued the Warning Letter, addressed to Martha. Publicly reported on December 15, 2021, the Warning Letter noted the more than 74,000 retainer ring complaints reported from June 2016 through November 2019, with over 57,000 of those reported to the FDA as MDRs. The FDA found that although Medtronic offered "an update to the planned corrective actions," Medtronic "did not provide documentation or evidence that all the corrections and corrective actions . . . have been implemented and completed as they are still in progress." Accordingly, the FDA warned:

> Failure to promptly correct these deficiencies may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to seizure, injunction, and civil money penalties. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will not be approved until the deficiencies have been corrected.

208. Salmon's personal and consistent involvement in communications with the FDA during and after the inspection supports an inference of his personal knowledge ***and*** the knowledge of the other members of Medtronic's Executive Committee, which included Martha, Parkhill, and Lerman. In fact, Martha explained during the October 14, 2020 Investor & Analyst Meeting that the Executive Committee all "sit around in a monthly meeting" to discuss, among other things, strategic issues affecting the Company. And in its December 14, 2020 press release announcing Salmon's promotion to EVP and President Cardiovascular Portfolio, Medtronic noted that Salmon worked "closely with the other portfolio leaders and members of the Executive Committee on enterprise level strategy and value creation."

C. Defendants' Regular Communication with the FDA Supports an Inference of Scienter

209. Throughout the Class Period, Defendants emphasized their regular communications with the FDA, further supporting a compelling inference that they knew that (i) the MiniMed 600 Series was under the FDA's scrutiny for a recall, and (ii) the FDA's scrutiny of the MiniMed 600 Series jeopardized the FDA's approval of the MiniMed 780G pump.

210. For example, when Ishrak responded to an analyst question about the strategy of maintaining the Diabetes Group within Medtronic (as opposed to divesting the group) at a June 11, 2019 Goldman Sachs Global Healthcare Conference, he explained that the Diabetes Group was served by Medtronic having "a seat at the table with the FDA" for rules concerning clinical trials and setting product standards. He later reiterated on September 10,

2019 at Morgan Stanley Healthcare Conference that Medtronic's "breadth with the FDA" was a factor contributing to the Diabetes Group's successful future as part of Medtronic. Likewise, discussing the MiniMed 780G's submission to the FDA during the Q3 2020 earnings call on February 18, 2020, Salmon affirmed to investors: "We're very interactive with [the] FDA. In fact, we'll be meeting with them later this week."

211. Even during the COVID pandemic, Defendants pointed investors to their close working relationship with the FDA, as Salmon did during the May 27, 2021 Q4 2021 earnings call with analysts when asked about the approval for the MiniMed 780G pump:

> I don't have an update on the timing. We're in active review, as Geoff said on the filing. And we – the reviewer that's working with us is the same one that reviewed the 770 device. So we think that, that familiarity is going to be helpful. But there's no update on timing at this point.

212. In fact, Defendants further noted that the FDA's involvement in the COVID crisis was "good in some ways because ***we've been very collaborative*** about what the right kind of cadence is for filing" for FDA approval of the MiniMed 780G pump.

213. Salmon repeated the same message during a question-and-answer session at a June 2, 2021 Jefferies Healthcare Conference:

> And I think what's good for us is the FDA understands how important this product is. They're very sympathetic to that. We're in active review right now. The reviewer who's assigned to the 780G as well as the rest of the products to Zeus is the same one that was on the 770G. So the hardware is well known to this reviewer and the review team. It's really a question of the software or the upgrade path or over-the-air security, that kind of stuff. So we hope that there's a good glide path toward a smooth review. But they've really been prioritizing COVID, of course, over other things right now.
>
> But I mean good ***familiarity is always important. Good connections with those reviewers is important***.

214. Repeatedly, Defendants noted to analysts that they were in "***active review***" with the FDA concerning the MiniMed 780 pump, which Martha highlighted on May 27, 2021 and November 23, 2021, and further, that the FDA was "***actively reviewing our files now***" on June 8, 2021. Salmon likewise commented on the FDA's "***active review***" on May 27, 2021 and June 2, 2021.

215. As late as November 23, 2021, after the inspection, Form 483, and subsequent correspondence with the FDA, and less than a month before the FDA's issuance of the Warning Letter, Salmon assured investors of the "very good interactive conversations with FDA":

> In the U.S., we have just – we're waiting for that approval to come through, and ***we've had very good interactive conversations with FDA***.

216. Defendants, having themselves described their close personal relationships with the FDA and the FDA's review of the MiniMed insulin pumps as "active," knew that the FDA's review was raising increasing concerns that led to the FDA announcement of a Class I recall and jeopardized MiniMed 780G's approval and launch. In addition to Medtronic's longstanding regulatory relationship with the FDA, Defendants' continuing interactions with the FDA during the Class Period supports a strong inference that Defendants were aware of the risk facing the MiniMed business. These interactions include the increasing number of consumer complaints Medtronic submitted to the FDA; the FDA's Class I recall on February 12, 2020; the FDA's facility inspection of the Diabetes Group's headquarters in Northridge in June and July 2021; the FDA's issuance of the Form 483 to Medtronic on July 7, 2021, and the subsequent communications between Medtronic and the

FDA through December 2021. Thus, there is a strong inference that as a result of Defendants' "interactive conversations" with the FDA, Defendants were fully aware of the FDA's increasing concerns relating to the MiniMed pumps, and the severe risks posed by the Class I recall and Warning Letter.

D. Ishrak and Martha (as CEO), Parkhill (as CFO), and Lerman (as General Counsel) Were Routinely Apprised of the Product Quality Failures and FDA Inspections

217. As members of the Board of Directors, Ishrak and Martha were routinely apprised of quality and FDA regulatory issues, including the MiniMed 600 issues and the FDA inspections arising from the recall, by the Quality Committee, whose mission is to assist the Board in its oversight of the quality and safety of Medtronic's products. The Quality Committee presented to the Board regarding, among other things, "***the Company's response to quality and quality system assessments conducted by the Company and by external regulators*** (including without limitation FDA and various notified bodies)" and "***the Company's response to material quality and field actions***." The Quality Committee "may request any director, officer or employee of the Company or the Company's outside counsel to attend a meeting of the Committee or to meet with any members of, or consultants to, the Committee." Moreover, the Quality Committee "report[ed] on its activities to the Board ***regularly***." Accordingly, Ishrak and Martha, as members of the Board, were regularly apprised of the quality and regulatory issues alleged herein.[13]

[13] Further supporting his scienter, Ishrak was named as a defendant in a 2015 complaint filed by the Department of Justice relating to violations of FDA regulations with regard to a Medtronic infusion pump, which found that he and his fellow defendants were "well aware that their practices violate" federal regulations, and that the "FDA has repeatedly warned

218. The Medtronic Code of Ethics for Senior Financial Officers, which implicates to Ishrak and Martha (as CEO), Parkhill (as CFO), and Lerman (as General Counsel), further supports scienter. The Code of Ethics for Senior Financial Officers provides that "[t]he CEO and all Senior Financial Officers[14] are responsible for full, fair, accurate, timely, and understandable disclosure in the reports and documents that the Company files with, or submits to, the SEC and in other public communications made by the Company." It also requires that the CEO and/or each Senior Financial Officer "promptly bring to the attention of the General Counsel or the CEO any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings." The Code of Ethics for Senior Financial Officers further provides that "[t]he CEO and each Senior Financial Officer shall promptly bring to the attention of the General Counsel or the CEO any information he or she may have concerning evidence of a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof, or any violation of this Code of Ethics."

E. Defendants Were Hands-on Executives Who Closely Monitored the Diabetes Group and Its Insulin Pump Business

219. Leading into and during the Class Period, the Diabetes Group had persistently under-delivered, with Defendants and market analysts alike recognizing the Diabetes

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Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with" federal regulations. *United States v. Medtronic Inc.*, No. 0:15-cv-02168, ECF 1 (D. Minn. Apr. 27, 2015).

[14] The Code of Ethics for Senior Financial Officers defines "Senior Financial Officers" to include "the CEO and the CFO, Treasurer and Corporate Controller and other senior financial officers performing similar functions who have been identified by the CEO."

Group's shaky performance. As a result, Defendants were intently focused on the group's performance, and specifically the performance of its insulin pump technology, as they themselves publicly asserted.

220. Market analysts' attention on the Diabetes Group meant that Defendants likewise kept close focus on its developments and setbacks. As the Class Period began, market analysts questioned Defendants about whether the Diabetes Group should even remain within Medtronic (as opposed to being divested by the Company):

- Morgan Stanley, May 23, 2019: "[D]o you think an independent Diabetes business would allow you to adapt or grow more quickly?"
- Goldman Sachs, June 11, 2019: "Do you think strategically it makes sense for you to hang on to this business in the medium term or might it be better served by not being part of Medtronic?"
- Morgan Stanley, September 10, 2019: "I was going to talk about – one of the business that struggled is Diabetes. You and I talked about this. We said – 1.5 years ago, we made the case of could this business be in a better position if it was outside of Medtronic. You spin Diabetes, you reinvest. . . . Why is this asset still best positioned inside Medtronic?"
- Barclays, March 11, 2020: "[T]he one area that continues to be a little bit of a drag is Diabetes. I just wanted to touch on that. How confident are you . . . that Medtronic can turn this around?"

221. To respond to analysts' queries concerning the viability of the Diabetes Group, Defendants assured investors that they were focused on the Diabetes Group's performance, with particular attention focused on the 780G pump's U.S. approval and launch.

222. Defendants personally spoke about the Diabetes Group generally and the MiniMed 600 Series and/or 780G pumps specifically ***every*** quarter during the Class Period. In fact, on the Q2 2020 earnings call, shortly after Martha became Medtronic's President, he called out the Diabetes Group's turnaround as one of his top three priorities, along with

maintaining Medtronic's mission statement and growing market share throughout the Medtronic portfolio. Specifically, Martha affirmed on November 19, 2019 that "***[r]einvigorating our Diabetes business is also a priority***." Speaking on the same call, Ishrak noted that Medtronic was "going to go through a period of some pressure" and stated that the pipeline with the 780G pump was "***an area of focus for us***."

223. Six months later, at a May 29, 2020 Sanford C. Bernstein Strategic Decisions Conference, Martha reconfirmed his focus on the Diabetes Group and the deep dive he took into the business when he took over as CEO:

> The other one is diabetes. It's a big market. I talked about it being – we're being behind there. And a lot of questions. Just to be frank, people question, is Medtronic like the right owner? And we haven't really managed that business well. I got to kind of accept that critique that we haven't, I don't think. But I – as we put a new leadership in there and ***we've taken a hard look at it and for me coming in new, it's an opportunity to relook at it. And we did that***.

224. Later, on September 14, 2020, Martha gave further detail of Defendants' review of the Diabetes Group, and specifically Salmon's investigation into the Diabetes Group's technology following his appointment as the group leader:

> So Sean went in 6 months or so ago, it seems like a long time, but he – and validated the technologies there.
>
> So one of the things I was concerned about is, is the technology really there? And is our pipeline legit. ***Him and the team came back and we spent a lot of time on this,*** and the answer is yes. Like even in sensors.

225. Thereafter, Defendants continued to reiterate that they were closely managing the problems in the Diabetes Group. For example, during the November 24, 2020 Q2 2021 earnings call, Martha stated: "[W]e're ***laser-focused*** on doing what it takes to return to market growth [in Diabetes]." In a December 14, 2020 Medtronic press release, Salmon was

quoted: "Completing the turnaround in Diabetes remains a ***high priority for me***." Likewise, at the Cowen Healthcare Conference on March 2, 2021, Parkhill noted: "Obviously, getting Diabetes back to market growth has been a ***key strategic focus*** and ***imperative for our company***." Thus, as Medtronic's executive management assured investors, Defendants were closely in tune with the Diabetes Group's performance and the anticipated launch of the MiniMed 780G pump.

226. Insiders confirmed Defendants' involvement in the Diabetes Group. For example, CW-2 – a former Senior Director of US Regulatory Affairs who managed a team of regulatory employees responsible for gaining the FDA's approval for MiniMed 780G – reported that the management team at Medtronic was very hands-on, with "all developments in the Diabetes units [being] reported up the chain of command to the CEO." In particular, CW-2 recalled that "we were reporting on the 780G's progress during the monthly standing project review meetings," whose participants included executive management members, including Salmon and Parkhill. CW-2 noted that the most important topic for these meetings was the anticipated timelines for FDA approval and recalled that Medtronic's executive management, which included Martha, Parkhill, and Salmon, had closely monitored the progress of the MiniMed 780G's FDA approval because "***this was our live or die product***."

F. High-Level Departures During the Class Period Support Scienter

227. The departures of Ishrak, Hakami, and Lerman also support a strong inference of scienter. On August 28, 2019, Medtronic announced that Ishrak was stepping down as CEO effective April 27, 2020, to be replaced by Martha. The announcement of Ishrak's

departure from Medtronic coincided with Medtronic releasing redesigned retainer rings for the MiniMed 600 Series insulin pumps in August 2019, and just before Defendants' November 2019 Field Safety Notification, which the FDA later determined was, in fact, a Class I recall.

228. Also, around the same time and as problems were increasing for the MiniMed 600 Series, Hakami, the President of the Diabetes Group, was replaced by Salmon on October 21, 2019. This occurred just prior to Defendants' November 2019 Field Safety Notification, which disclosed the MiniMed problems for the first time (albeit incompletely). As Martha later explained on September 14, 2020: "[W]e've made some changes in Diabetes and that leadership team and a few other spots where we felt like we really needed to make those change[s]."

229. Finally, on June 24, 2021, Lerman notified Medtronic's Board that he was retiring from the Company effective as of December 31, 2021. Based on Medtronic's Code of Ethics, Lerman, as Medtronic's General Counsel, was "promptly" apprised of "material information" that "affects the disclosures made by the Company" and "any information" that "may" be evidence of a material violation of securities or other laws, rules, or regulations applicable to the Company and the operation of its business. With such information in hand, Lerman announced his exit from the Company as the FDA's inspection of the Northridge facility was in full swing.

G. Defendants Were Motivated to Mislead the Market Regarding the Quality Issues in the MiniMed 600 Series to Buy Time Until the FDA's Approval of the MiniMed 780G Pump

230. The FDA's approval of the MiniMed 780G insulin pump was a prerequisite to launching that product in the United States, which was vital to Medtronic regaining its leadership and market share in the diabetes market. Indeed, Hakami acknowledged at the June 9, 2019 Investor and Analyst Briefing from ADA that "we're sort of off cycle from an innovation standpoint in the U.S. That's just a fact, all right? So the 670G is going to be 3 years old in September in the United States." To secure the FDA's approval of the MiniMed 780 pump, Defendants were motivated to mislead the market when detailing the scope and seriousness of the quality problems with Medtronic's prior insulin pumps.

231. According to Ishrak at a May 29, 2019 Sanford C. Bernstein Strategic Decisions Conference, Medtronic focused on the insulin pump market because "that's where we're leaders and we intend to be leaders," and because it "is a high growth" market. Yet, Defendants blamed increased "competitive challenges" – not customers fleeing product defects and malfunctions – as they acknowledged Medtronic's slipping market share. This was a message Defendants repeated throughout the Class Period. For example, one year later, at a May 29, 2020 Sanford C. Bernstein Strategic Decisions Conference, Martha addressed the slide in the Diabetes Group's performance despite the large diabetes market size: "Our diabetes business, the diabetes market is a big market. Big patient need. We have a market-leading position in the type 1 space. But we're losing share there. ***We've got to reinvigorate that business***. . . ."

232. Having seen the MiniMed 600 Series problems and stagnating sales, Defendants introduced the MiniMed 780G pump, which they repeatedly pointed to as a growth driver. For example, on September 10, 2019, Ishrak pointed to the 780G as "***growth driver*** that we have coming in." And on January 13, 2020, Ishrak remarked that for the MiniMed 780G pump, "FDA submission is forthcoming. And this is, again, a product that's forthcoming and ***will move the needle for us in diabetes***." After taking over as President of the Diabetes Group, Salmon stated on a February 18, 2020 earnings call: "***The 780G is an important catalyst for us to drive growth***." Parkhill likewise noted on September 14, 2020 in response to an analyst question: "We recognize that we have product gaps, too, that we are focused on closing. ***We'll start to close that with the 780G***, and we – then we'll focus on closing it even more when we can launch greater continuous glucose monitors in the form of both Zeus and then ultimately, synergy." When asked on September 14, 2020 about the strategy to get the Diabetes Group back on track, Martha reiterated the same message: "we're starting to see the internal milestones have accelerated. And we believe that on all fronts, ***when the 780 comes out, that going to be a big jump forward for us***."

233. With the MiniMed 780G pump's launch in Europe in June 2020, Defendants reported the positive patient response and their drive to achieve the same results in the United States. For example, Michael Weinstein, Medtronic's SVP of Strategy, said at the December 3, 2020 Evercore ISI HealthCONx Conference:

> [T]he feedback in Europe on 780G is phenomenal. It's the – we get it every day in the patients that initially were in the trial and now that it's been commercialized, it is a whole new world for the customer feedback on a Medtronic pump relative to what we had with the 670G and the early challenges there.

* * *

> And we have this very – Medtronic has this very large installed base of patients that could be upgraded from a 670G today to our current product, 770 and then 780. We want to be able to offer that to patients as quickly as possible.

234. Martha likewise noted at the January 11, 2021 JPMorgan Healthcare Conference that "the 780G in particular has had tremendous customer response in Europe, which bodes well for when we bring this technology to the U.S. market." He later reiterated at the March 2, 2021 Cowen Healthcare Conference the expectation of seeing Europe's reception to the MiniMed 780G pump repeated in the United States:

> I would say the good news is that Diabetes is right now on a steady climb, back to market growth. And it's driven by some of the new products that we've introduced, particularly the 780G in Europe where we've seen really great strong reception for that product. Very strong new patients start on that product. And we're excited to eventually get approval for that in the United States and see that happen across the United States as well.

235. With the message that the MiniMed 780G pump would resuscitate the Diabetes Group and drive revenue growth, particularly after strong results were posted in Europe, Defendants were motivated to mislead investors about the mounting quality issues that imperiled approval of the MiniMed 780G.

H. The Impact on Medtronic's Overall Business Supports Scienter

236. As discussed above, Medtronic announced the FDA's issuance of the Warning Letter on December 15, 2021. At that time, Defendants also announced that while the Company did "not expect an impact to the total company organic revenue growth and adjusted earnings per share guidance for the third quarter or full fiscal year 2022 that it issued on November 23, 2021," it did expect an impact on the Diabetes Group's organic

revenue and further modeled that for FY23, the impact on the Company's 2023 revenue growth was 0.5% to 1%.

237. Then, on May 26, 2022, Medtronic told investors during its Q4 2022 earnings call that the Company no longer expected to receive timely FDA approval for the MiniMed 780G, and therefore had "***elected not to include it in our guidance***" for its FY23 revenue. The Company further announced that it expected the Diabetes Group's organic revenue growth to decline 6% to 7%. To put the impact of this revenue miss in context, ***one percentage point of FY23 revenue growth is equal to approximately $325 million in revenue***. Medtronic's extreme step of not including the MiniMed 780G pump in its guidance contributes to the inference that the quality problems identified in the Warning Letter were material, and were therefore known by Defendants during the Class Period.

238. In addition, U.S. patients who had been waiting for the MiniMed 780G's approval now turned to competitor products. As Salmon explained on Medtronic's May 26, 2022 Q4 2022 earnings call: "So within the U.S., the dynamic is obviously people waiting for the new technology to come before prescribing it for new patients or some patients not wanting to wait for it and moving on to competitive therapies." Following the Class Period on Medtronic's November 22, 2022 Q2 2023 earnings call, the new President of the Diabetes Group, Que Dellara, admitted that the U.S. market was facing "attrition." Martha, meanwhile, acknowledged at the November 29, 2022 Evercore ISI HealthCONx Conference that the Warning Letter had created a "log jam" for a "a lot of technology" "that we're getting further along outside the U.S. in terms of regulatory approvals." The long-term financial and competitive effects of failing to obtain approval for the MiniMed 780G pump

contributes to an inference that Defendants knowingly concealed the risk that the FDA would not timely approve the MiniMed 780G pump.

I. Defendants' SOX Certifications Support an Inference that Material Information Relating to Product Complaints, the MiniMed Recall, and the Warning Letter Was Made Known to the Certifying Defendants

239. Defendants' scienter is also underscored by the SOX certifications signed Ishrak and Parkhill, until Ishrak's departure, and then by Martha and Parkhill. These certifications acknowledged their responsibility to investors for establishing and maintaining controls to ensure that material information about Medtronic was made known to them and that the Company's disclosure controls and financial reporting controls were operating effectively.

240. During the Class Period, Ishrak, Martha, and Parkhill certified that they had undertaken an assessment and evaluation of the Company's disclosure controls to ensure that Medtronic's SEC filings did not contain any false information, including controls designed to ensure all relevant and material information was reviewed by Ishrak, Martha, and Parkhill prior to certifying those filings pursuant to SOX. This further establishes that these Defendants knowingly misled the market, or were reckless in making such representations and executing such certifications, because Ishrak, Martha, and Parkhill were, at that time, aware of and/or recklessly disregarded material weaknesses in Medtronic's system of internal controls concerning financial reporting and disclosures regarding the same that were not disclosed to the investing public.

J. Insider Stock Sales Support a Motive to Commit Fraud

241. Martha, Salmon, Hakami, and Lerman were motivated to engage in their deception to capitalize on an artificially increased stock price by selling a total of 368,308 shares of their personally held Medtronic stock during the Class Period, for gross proceeds of more than ***$42.8 million***. As demonstrated below, these Defendants' sales were unusual in timing and amount, executed to maximize personal benefit from the fraud. Their Class Period sales also represented significant proportions of each Defendant's total shares held during the Class Period:

Insider	Date	Price	Shares Sold	Proceeds	Est. Profit	% Sold
Geoffrey Martha (CEO, as of April 27, 2020)	6/6/2019	$96.05	11,000	$1,056,550		
	4/5/2021	$118.83	11,712	$1,391,737		
	6/28/2021	$125.29	11,500	$1,440,835		
	8/25/2021	$132.67	11,581	$1,536,451		
			45,793	$5,425,573	$2,654,008	7.5%
Sean Salmon (EVP, Diabetes, Oct. 21, 2019 to May 2, 2022; continuing as EVP, Cardiovascular)	8/25/2021	$134.09	7,290	$977,516		
	8/25/2021	$134.08	21,129	$2,832,976		
			28,419	$3,810,492	$2,711,998	44.0%
Hooman Hakami (EVP, Diabetes, May 13, 2014 to Oct. 21, 2019)	6/12/2019	$97.49	52,664	$5,134,213		
	9/10/2019	$107.22	2,191	$234,919		
	9/10/2019	$107.09	10,000	$1,070,900		
	9/10/2019	$107.31	10,257	$1,100,679		
	9/10/2019	$107.41	33,175	$3,563,327		
	9/10/2019	$107.28	27,254	$2,923,809		
			135,541	$14,027,847	$5,688,169	81.5%
Bradley Lerman (SVP, General Counsel, May 2014 to Dec. 31, 2021)	8/2/2019	$102.02	6,599	$673,230		
	8/5/2019	$100.31	4,000	$401,240		
	10/8/2020	$110.00	20,714	$2,278,540		
	11/9/2020	$113.13	20,715	$2,343,488		
	12/22/2020	$115.56	2,605	$310,034		
	8/2/2021	$131.52	4,000	$526,080		
	8/31/2021	$134.17	50,775	$6,812,482		
	9/30/2021	$126.58	49,147	$6,221,027		
			158,555	$19,557,121	$10,623,690	27.1%
	Total:		**368,308**	**$42,821,033**		

242. The sales were suspiciously timed because they corresponded with the escalating issues facing the MiniMed 600 Series pumps and increasing uncertainty of FDA approval for the next-generation MiniMed 780G pump, and were often executed just after misleading statements, or just prior to disclosures that removed artificial inflation from the price of Medtronic stock.

243. ***Martha.*** Martha was motivated to engage in the fraudulent course of conduct alleged herein to sell over 45,000 shares of Medtronic common stock, from which he gained $5.4 million in proceeds and nearly $2.7 million in profits. These sales were unusual in timing because they occurred while Defendants concealed problems with the MiniMed pumps. First, Martha dumped 11,000 Medtronic shares in June 2019, when Medtronic had received more than 74,000 customer complaints, which led to Medtronic redesigning and reissuing its MiniMed 600 Series pump. Next, Martha sold another 11,712 shares in April 2021, just after Medtronic revised its risk assessment protocol in March 2021 to continue manufacturing an artificially low probability of harm such that Medtronic could avoid a full recall of all MiniMed 600 Series pumps.

244. Just two months after Martha made his second sale, the FDA commenced its month-long inspection of the Northridge facility on June 7, 2021. On June 28, 2021, Martha made his third sale of 11,500 Medtronic shares for proceeds of $1.4 million – just as FDA inspectors were in the middle of their inspection, and as Medtronic stock traded near its Class Period high. In Martha's last Class Period sale on August 25, 2021 – ***the day after*** he personally made misrepresentations concerning the approval of the MiniMed 780G – he gained proceeds of over $1.5 million, as Medtronic was struggling to address the severe,

numerous issues cited by the FDA in its Form 483, and when Medtronic's stock was trading near its Class Period high. These sales were suspiciously timed and support an inference of Martha's scienter.

245. ***Salmon***. On August 25, 2021, in one single day, Salmon dumped almost half of his Medtronic holdings for proceeds of $3.8 million, raking in a one-day profit of $2.7 million, when Medtronic's stock price was trading near its Class Period high. Beyond the extraordinary size, amount, and impeccable timing, the sale was unusual because Salmon had not sold any shares prior to the Class Period. Additionally, the timing of these two sales is incredibly suspicious because they were made ***the day after*** Salmon personally made misrepresentations concerning the approval of the MiniMed 780G. The timing of Salmon's sales was also suspicious because they closely followed the FDA's inspection of the Northridge facility, and occurred during the period that he personally struggled to address the severe, numerous problems identified by the FDA in the form of multiple letters to the FDA authored and signed by Salmon himself. Critically, neither of Salmon's two sales were made pursuant to a Rule 10b5-1 plan.

246. ***Hakami***. Hakami cashed out almost all of his Medtronic holdings – nearly 82% – before leaving the Company on October 21, 2019 as the President of the Medtronic Diabetes Group, with less than six years at the Company and as scrutiny over the Diabetes Group was intensifying. Hakami's stock sales on September 10, 2019, for proceeds of nearly $9 million, and his subsequent departure were expediently and suspiciously timed because only a month later, on November 21, 2019, the increased complaints concerning the MiniMed 600 Series led Medtronic to issue a safety notification concerning the MiniMed

600 Series with a clear retainer ring (albeit one that failed to notify users of the full extent of the problems). Shortly thereafter, in February 2020, the FDA classified the notification as a Class 1 recall, causing the stock price to decline.

247. Compared to the year before the Class Period, Hakami's sales were unusual in amount, as they were more than double and triple his two sales in 2018, which had proceeds of $2.2 million on January 5, 2018 and $2.5 million on August 31, 2018. While Hakami's sales were made pursuant to a Rule 10b5-1 plan, his outsized sales bringing in proceeds of $5.1 million and $8.9 million on June 12, 2019 and September 10, 2019, respectively, were notable for their proximity to the mounting problems in advance of Hakami's departure.

248. As Hakami began his exit from his Medtronic holdings, analysts questioned the Diabetes Group's performance, noting on May 29, 2019, for example, that the business had "slowed"; on June 10, 2019, that it "struggled"; and on August 20, 2019, that the Company had "switched the guidance to the low end of the range" for the Diabetes Group. Yet Defendants maintained an upbeat message about Medtronic's upcoming pipeline, emphasizing, for instance on August 20, 2019, the "product launches that we're anticipating in the second half. Those are on time." Hakami agreed, stating, the "pipeline . . . remains on track." On June 9, 2019, just days before Hakami's first Class Period sale, he deflected concerns regarding quarter-to-quarter "lumpiness" in the Diabetes Group, and assured investors that "670G is going to be ramping up even more in FY '20." When asked point blank by an analyst, "what's impacting your business negatively right now, most?" and whether "it [was] more 670G dynamics," Hakami suggested that increased competition after three years on the market was a headwind, but withheld all details of the increasing numbers

of customer complaints concerning the damaged pumps and retainer rings. Rather, Hakami suggested deceptively that Medtronic was facing "dynamics that . . . all of the pump companies are dealing with":

> One, if you were to take a look at some of the headwinds that we have with respect to the new patient dynamic, I would say there's a couple. One, we're sort of off cycle from an innovation standpoint in the U.S. That's just a fact, all right? So the 670G is going to be 3 years old in September in the United States. Now the competition has introduced new products, and we're sort of still in the cycle of getting some of these things that we talk about. So there is that element of it. And then there's other dynamics that we're dealing with, all of the pump companies are dealing with, CGM first and those types of things in the U.S.

249. With the defective MiniMed 600 Series requiring a redesign and reissuance starting in August 2019, after Medtronic had received tens of thousands of complaints and masked the need to issue a recall by engaging in flawed risk assessments, Hakami sold on September 10, 2019 another almost $9 million of his Medtronic shares, bringing his total profits from insider selling to $5.7 million in less than three months.

250. ***Lerman***. From August 2019 through September 2021 – taking advantage of Medtronic's inflated share prices – Lerman sold nearly 159,000 Medtronic shares for proceeds of $19.6 million. These sales amounted to over a quarter of his Class Period holdings, permitting Lerman to pocket $10.6 million in profits. As Class Period sales, they were suspicious in timing because they coincided with the concealment of the quality problems relating to the MiniMed 600 Series and their impact on the FDA's approval of the MiniMed 780G pump. The majority of Lerman's sales were made while he was aware, as General Counsel, of the increasing number of customer complaints and product liability cases brought against the Company for the failed retainer rings. Moreover, per the

Company's Code of Ethics for Senior Financial Officers, he was informed of the potential "material violations" of FDA regulations related to the MiniMed pumps and customer complaints. Even more suspicious, nearly two-thirds of Lerman's Class Period sales, amounting to 103,922 shares for proceeds of $13.6 million, occurred in the weeks following the FDA's inspection of the Northridge facility, as Medtronic was "taking actions to address each of the three observations in the FDA 483" and drafting response letters to the FDA to update it on "the actions that will be taken to address the observations" (as reported by Medtronic in its July 28, 2021 letter to the FDA). Lerman's August and September 2021 sales – like the August 2021 sales by Martha and Salmon – occurred just after the non-public FDA inspection, when Medtronic's stock price was near its Class Period high, and just before artificial inflation was removed from the stock price by the issuance of the Warning Letter. Moreover, these were out of line with Lerman's pre-Class Period sales: Lerman had previously made only one sale of less than 9,000 Medtronic shares in June 2018.

XI. LOSS CAUSATION

251. Defendants' wrongful conduct, as alleged herein, directly and proximately caused Plaintiff's and Class members' economic loss. Plaintiff's claims for securities fraud are asserted under the fraud-on-the-market theory of reliance. The markets for Medtronic's common stock were open, well-developed, and efficient at all relevant times. During the Class Period, as detailed herein, Defendants engaged in a scheme and made misleading statements and omissions regarding product quality issues with the MiniMed 600 Series pumps and the approval of the MiniMed 780G pump. Defendants' conduct artificially inflated the price of Medtronic common stock and operated as a fraud or deceit on the Class.

252. The Class Period inflation in Medtronic's stock price was removed when information concealed by Defendants' scheme and misleading statements and omissions was revealed to the market. The information was disseminated through partial disclosures that revealed the nature and effect of Defendants' alleged conduct. These disclosures, as more particularly described below, removed artificial inflation from Medtronic common stock, causing economic injury to Plaintiff and other members of the Class.

253. The corrective impact of the partial disclosures during the Class Period alleged herein, however, was tempered by Defendants' continued scheme and misleading statements that continued to conceal the true nature and extent of Defendants' fraud. Each partial disclosure did not on its own fully remove the inflation from Medtronic's stock price, because it only partially revealed the nature and extent of the fallout from Defendants' previously misrepresented and concealed conduct. Defendants' continued scheme, misrepresentations, and omissions maintained the price of Medtronic common stock at a level that was inflated by fraud, inducing members of the Class to continue purchasing shares in Medtronic even after Defendants' partial disclosures.

254. The disclosures that corrected the market price to eliminate the inflation maintained by Defendants' fraud are detailed below. These stock price declines were due to firm-specific, fraud-related disclosures and not the result of market, industry, or firm-specific, non-fraud factors. The following stock price declines and descriptions thereof are not necessarily comprehensive since fact and expert discovery are not complete.

255. A partial disclosure entered the market on February 12, 2020, when the FDA announced a Class I recall – the most serious type of recall – of the MiniMed 600 Series

insulin pumps, which expanded the scope of the issues with these products beyond Medtronic's earlier Field Safety Notification in November 2019. As a result of this partial disclosure, the price of Medtronic stock declined more than 2% on volume of more than 7.6 million shares to close at $116.49 per share on February 12, 2020. In contrast to the decline in Medtronic common stock, the S&P 500 Index and the S&P 500 Health Care Equipment Index both increased slightly during this period.[15] Analysts commented on the disappointing news and attributed Medtronic's stock price decline to the announcement of the Class I recall. For example, an analyst at Evercore ISI stated, "MDT shares are off on a Street Account article highlighting the recall of its 670G insulin pumps . . . ." Although the stock price reacted negatively to the February 12, 2020 announcement of the Class I recall, the reaction was tempered because, according to Evercore ISI, Medtronic indicated it "believes the occurrence of 'retainer ring breaking' is less than 0.1%" and it "told its customer that it will replace a small number of pumps that have the damaged rings – cost impact expected to be minimal." Defendants' continued scheme and misleading statements and omissions regarding Medtronic's prospects maintained artificial inflation in the price of Medtronic common stock.

256. On December 15, 2021, Medtronic revealed that it had received the Warning Letter from the FDA regarding the Northridge facility. Specifically, Defendants stated that the Warning Letter "was issued following an inspection that concluded in July 2021 related

[15] For purposes of comparing its stock price performance vis-à-vis its peers and relevant market, Medtronic referred investors to the S&P 500 Index and the S&P 500 Health Care Equipment Index.

to recalls of the MiniMed™ 600 Series insulin infusion pump" and other products, and that "[t]he warning letter focuses on the inadequacy of specific medical device quality system requirements at the Northridge facility in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events." That same day, Medtronic announced that as a result of the Warning Letter, including new "uncertainty on the timing of U.S. Diabetes product approvals," the Company was "adjusting its expectations for its Diabetes business organic revenue." Specifically, Medtronic lowered its Diabetes Group guidance, announcing "declines in the high-single digit range for the third fiscal quarter and the mid-single digits range for the full fiscal year 2022, down modestly from previous guidance of mid- and low-single digit declines, respectively." On December 16, 2021, Defendants held an analyst meeting where they further discussed the fallout from the Warning Letter. On December 17, 2021, J.P. Morgan downgraded Medtronic shares, citing "setbacks to the company's marquee pipeline assets," including the MiniMed 780G. As a result of these disclosures, the price of Medtronic stock declined more than 9.9% on volume of more than 59.5 million shares to close at $100.63 per share on December 17, 2021. In contrast to the sharp decline in Medtronic common stock during this period, the S&P 500 Index was flat and the S&P 500 Health Care Equipment Index was up by approximately half-a-percent during this period.

257. On May 26, 2022, Medtronic issued a press release on Form 8-K announcing its financial results for the fourth quarter and full year of FY22. Defendants announced that Diabetes Group revenue decreased 3% for FY22. Further, Defendants disclosed that Medtronic expected even worse performance for the Diabetes Group in FY23, projecting that

Diabetes Group revenue would decline 6% to 7% year-over-year. On the earnings call the same day, Defendants admitted that the Company's 2023 projections assumed that the MiniMed 780G would not receive FDA approval in FY23. On the same call, Salmon acknowledged the Company still needed "to improve and sustainably improve the quality system," as outlined in the Form 483 and Warning Letter. As a result of these disclosures, the price of Medtronic stock declined 5.8% on volume of approximately 12.7 million shares to close at $99.44 per share on May 26, 2022. In contrast to the decline in Medtronic's stock price, the S&P 500 Index was up nearly 2% and the S&P 500 Health Care Equipment Index was flat during this period.

XII. APPLICABILITY OF THE PRESUMPTION OF RELIANCE AND THE FRAUD-ON-THE-MARKET DOCTRINE

258. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants engaged in a scheme and made public misrepresentations or failed to disclose material facts during the Class Period;
- the scheme, misrepresentations, and omissions were material;
- Medtronic common stock are traded in an efficient market;
- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- the Company's common stock was traded on the NYSE and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired, and/or sold Medtronic common stock between the time the defendants failed to disclose or

misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

259. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

260. Plaintiff and the members of the Class are also entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

XIII. THE PSLRA SAFE HARBOR DOES NOT APPLY

261. The Defendants are liable for any misleading forward-looking statement ("FLS") pleaded that were contained in Medtronic's registration statement because the PSLRA's Safe Harbor provisions do not apply to "a forward-looking statement . . . that is . . . contained in a registration statement of, or otherwise issued by, an investment company." 15 U.S.C. §78u-5(b)(2)(B).

262. In addition, Defendants' verbal "Safe Harbor" warnings accompanying its oral FLS issued during the Class Period were ineffective to shield those statements from liability.

263. The Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer at Medtronic who knew that the FLS was false.

XIV. CLASS ACTION ALLEGATIONS

264. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or

otherwise acquired Medtronic common stock during the Class Period (the "Class") and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein and the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

265. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Medtronic common stock was actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Medtronic or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

266. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

267. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

268. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether Defendants engaged in a scheme or course of business that operated as a fraud or deceit on investors;
- whether statements made by Defendants to the investing public during the Class Period misrepresented or omitted material facts about the business, operations, and management of Medtronic;
- whether Defendants caused Medtronic to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Medtronic common stock during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

269. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XV. CLAIMS

COUNT I
Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

270. Plaintiff repeats and realleges each and every allegation in ¶¶1-269 above as if fully set forth herein.

271. This Count is based upon §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder by the SEC. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and the Class in connection with their purchase of Medtronic common stock during the Class Period.

272. During the Class Period, the Defendants, during the time they held their positions at Medtronic, engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes, and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Medtronic securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Medtronic securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Defendants, and each of them, took the actions set forth herein.

273. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Medtronic securities. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Medtronic's finances and business prospects.

274. By virtue of their positions at Medtronic, the Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Defendants. Said acts and omissions were committed willfully or with reckless disregard for the truth. In addition, each of the Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

275. Information showing that the Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Defendants' knowledge and control. As the senior managers and/or directors of Medtronic, Defendants had knowledge of the details of Medtronic's internal affairs.

276. Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, Defendants were able to and did, directly or indirectly, control the content of the statements of Medtronic. As officers and/or directors of a publicly held company, Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Medtronic's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Medtronic securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Medtronic's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Medtronic securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or upon statements disseminated by Defendants, and were damaged thereby.

277. During the Class Period, Medtronic securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Medtronic securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Medtronic securities was

substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Medtronic securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

278. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

279. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Violations of §20(a) of the Exchange Act (Against All Defendants)

280. Plaintiff repeats and realleges each and every allegation in ¶¶1-279 above as if fully set forth herein.

281. During the Class Period, Defendants, during the time they held their positions at Medtronic, participated in the operation and management of Medtronic, and conducted and participated, directly and indirectly, in the conduct of Medtronic's business affairs. Because of their senior positions, they knew the adverse non-public information about Medtronic's business as alleged herein.

282. As officers and/or directors of a publicly owned company, Defendants had a duty to disseminate accurate and truthful information with respect to Medtronic's financial

condition and results of operations, and to correct promptly any public statements issued by Medtronic which had become materially false or misleading.

283. Medtronic had the power to control and influence the other Defendants, and other Company executives through its power to hire, fire, supervise and otherwise control the actions of its employees and their salaries, bonuses, incentive compensation and other employment considerations. By virtue of the foregoing, Medtronic had the power to influence and control, and did influence and control, directly or indirectly, the decision making of Defendants, including the content of their public statements.

284. Because of their positions of control and authority as senior officers, Defendants were able to, and did, control the contents of the various reports, press releases, and public filings which Medtronic disseminated in the marketplace during the Class Period concerning Medtronic's business and results of operations. Throughout the Class Period, Defendants exercised their power and authority to cause Medtronic to engage in the wrongful acts complained of herein. Defendants, therefore, were "controlling persons" of Medtronic within the meaning of §20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Medtronic securities.

285. Each of the Defendants, therefore, acted as a controlling person of Medtronic. By reason of their senior management positions and/or being directors of Medtronic, each of the Defendants had the power to direct the actions of, and exercised the same to cause, Medtronic to engage in the unlawful acts and conduct complained of herein. Each of the Defendants exercised control over the general operations of Medtronic and possessed the

power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

286. By reason of the above conduct, Defendants are liable pursuant to §20(a) of the Exchange Act for the violations committed by Medtronic.

XVI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that this action is a proper class action, and certify Plaintiff as a Class Representative under Rule 23 of the Federal Rules of Civil Procedure and appointing Robbins Geller Rudman & Dowd LLP as Class Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including reasonable attorneys' fees, accountants' fees, and experts' fees, and other costs and disbursements; and;

D. Awarding such other and further relief as this Court may deem just and proper.

XVII. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

DATED: February 14, 2023

ROBBINS GELLER RUDMAN
& DOWD LLP

s/DARRYL J. ALVARADO
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